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OCTOBER TERM, 1978

LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS, PETITIONER

v.

MALCOLM E. BERGY, ET AL

LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS, PETITIONER

v.

ANANDA M. CHAKRABARTY

PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF CUSTOMS AND
PATENT APPEALS

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The Solicitor General, on behalf of the Acting Commissioner of Patents and Trademarks, petitions for a writ of certiorari to review the judgments of the United States Court of Customs and Patent Appeals in these cases.¹

¹The two cases present a common legal issue and were decided by the Court of Customs and Patent Appeals in one opinion; we are therefore filing one petition to seek review of both judgments. See Rule 23.5 of the Rules of this Court.

OPINIONS BELOW

The most recent opinion of the Court of Customs and Patent Appeals (App. A, *infra*, 1a-103a) in these cases is reported at 596 F.2d 952.

The opinion of this Court remanding *Parker v. Bergy* to the Court of Customs and Patent Appeals is reported at 438 U.S. 902. The prior opinion of the Court of Customs and Patent Appeals in that case (App. C, *infra*, 106a-128a) is reported at 563 F.2d 1031. The opinion of the Patent and Trademark Office Board of Appeals (App. D, *infra*, 129a-139a), is reported at 197 U.S.P.Q. 78. The opinion of the patent examiner (App. E, *infra*, 140a-141a) is not reported.

The prior opinion of the Court of Customs and Patent Appeals (*In The Matter of the Application of Ananda M. Chakrabarty*) (App. F, *infra*, 142a-158a) is reported at 571 F. 2d 40. The opinions of the Patent and Trademark Office Board of Appeals (App. G, *infra*, 159a-164a) and of the patent examiner (App. H, *infra*, 165a-167a) are not reported.

JURISDICTION

The judgments of the Court of Customs and Patent Appeals were entered on March 29, 1979 (App. B, *infra*, 104a-105a). On June 13, 1979, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including July 27, 1979. The jurisdiction of this Court is invoked under 28 U.S.C. 1256. *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Dann v. Johnston*, 425 U.S. 219 (1976).

QUESTION PRESENTED

Whether a living organism is patentable subject matter under 35 U.S.C. 101.

STATUTES INVOLVED

35 U.S.C. 101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Plant Patent Act of 1930, 35 U.S.C. 161, provides in relevant part:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor * * *.

Section 42(a) of the Plant Variety Protection Act of 1970, Pub. L. No. 91-577 84 Stat. 1547, 7 U.S.C. 2402(a), provides in relevant part:

The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor * * *.

STATEMENT

A. *Bergy*

In 1974, Malcolm E. Bergy and two other scientists applied for a patent (B.R. 6-27),² assigned to the Upjohn Company (App. A, *infra*, 4a), with four claims to a process for preparing the antibiotic lincomycin using a newly isolated microorganism, *Streptomyces vellosus*

²"B.R." refers to the *Bergy* record; "C.R." refers to the *Chakrabarty* record.

("S. vellosus") (App. D, *infra*, 129a)³ and a fifth claim for a culture of *S. vellosus* itself, as follows (*ibid.*):

A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

The examiner allowed claims 1-4, and his decision on those claims is not in dispute (App. E, *infra*, 140a; App. A, *infra*, 27a). He rejected claim 5, however, on the basis that *S. vellosus* was a product of nature and thus not patentable (App. E, *infra*, 140a).

The Board of Appeals, with one member dissenting, sustained the rejection of claim 5 on the ground that a living organism is not patentable subject matter under 35 U.S.C. 101 (App. D, *infra*, 129a-139a). The Board found support for this view in the Plant Patent Act of 1930, 35 U.S.C. 161 *et seq.* It reasoned that Congress would not have specifically given patent protection under the 1930 Act to certain kinds of plants if it had believed that patents could already be obtained for these plants, as living organisms, under the general patent laws, R.S. 4886, now 35 U.S.C. 101 (App. D, *infra*, 130a-132a).⁴

³This microorganism was found in Arizona soil samples (B.R. 11) and a subculture, supplied by Upjohn, is permanently maintained by the Department of Agriculture at its research facilities. It is identified by its accession number, NRRL 8037 (App. D, *infra*, 129a).

⁴It did not reach the "product of nature" issue upon which the examiner's decision rested. The dissenting Board member concluded that claim 5 involved a "composition" or "manufacture" and was accordingly patentable under 35 U.S.C. 101 (App. D, *infra*, 132a).

The Court of Customs and Patent Appeals reversed, with two judges dissenting (App. C, *infra*, 106a). The court reasoned that, since patents are available for processes using a strain of living bacteria (*e.g.*, in septic systems or to produce alcohol), it would be "illogical" to insist that the living bacteria in a biologically pure culture are not themselves statutory subject matter (App. C, *infra*, 118a).

On June 26, 1978 this Court granted a petition for a writ of certiorari filed by the Solicitor General seeking review of the Court of Customs and Patent Appeals' decision, vacated the judgment and remanded the case to the Court of Customs and Patent Appeals "for further consideration in light of *Parker v. Flook*, 437 U.S. 584" (438 U.S. 902).

B. Chakrabarty

On June 7, 1972, Ananda M. Chakrabarty filed a patent application, assigned to the General Electric Company, with 36 claims to, *inter alia*, a strain of bacteria from the genus *Pseudomonas*, and an inoculum consisting essentially of these bacteria (C.R. 6-53, 118). Certain strains of *Pseudomonas* bacteria existing in nature are capable of degrading by enzymatic reactions a particular component of a complex hydrocarbon, such as crude oil, but no known, naturally-occurring bacterium can degrade more than one such component. Chakrabarty employed so-called "genetic engineering" to develop a *Pseudomonas* bacterium capable of degrading more than one component of crude oil (App. F, *infra*, 142a-143a).⁵

⁵Plasmids, which are hereditary units separate from the chromosomes, carry the hydrocarbon-degrading capacity of the cell. Chakrabarty utilized a process of natural conjugation (C.R. 8) to effectuate the transfer to a single cell of plasmids from various known strains of bacteria, each known to have a specific capacity to degrade a particular component of crude oil (C.R. 13, 25-33). The resulting organism, which Chakrabarty seeks to

Although the examiner allowed claims for the process by which incompatible plasmids present in a *Pseudomonas* bacterium are fused to render them compatible,⁶ he rejected those claims for the genetically engineered *Pseudomonas* bacteria themselves on two grounds: (1) the microorganisms are "products of nature"; and (2) as living organisms they are not patentable subject matter under 35 U.S.C. 101 (App. H, *infra*, 165a-167a; C. R. 117).

The Board of Appeals affirmed the examiner on the second ground (App. G, *infra*, 160a-163a).⁷ Relying on the legislative history of the Plant Patent Act, the Board reasoned that the terms "manufacture" or "composition of matter" in 35 U.S.C. 101 were not intended to cover living organisms (App. G, *infra*, 161a-162a). The Board also observed that if 35 U.S.C. 101 were interpreted to encompass genetically-modified bacteria, it could also be read to encompass modified living multicellular organisms (*ibid.*).

The Court of Customs and Patent Appeals reversed, with two judges again dissenting (App. F, *infra*). The majority found the case indistinguishable from its recent decision in *Bergy* (App. F, *infra*, 147a-148a).

patent, is a bacterium with separate hydrocarbon-degrading pathways representative of each kind of plasmid so incorporated (App. F, *infra*, 143a).

⁶The examiner also allowed claims 30-32 and 35-36, which were for an inoculum comprised of a carrier material able to float on water and of *Pseudomonas* bacteria containing at least two stable energy-generating plasmids, each providing a separate hydrocarbon-degrading pathway (C.R. 118).

⁷The Board rejected the product-of-nature theory partially relied upon by the examiner, noting that *Pseudomonas* bacteria containing two or more energy-generating plasmids are not naturally occurring (App. G, *infra*, 163a).

On July 26, 1978, the Solicitor General filed a petition for a writ of certiorari seeking review of the Court of Customs and Patent Appeals' decision (No. 78-145). Shortly thereafter, however, that court vacated its earlier judgment, recalled its mandate and restored the appeal to the calendar. On August 25, 1978, pursuant to the parties' stipulation, the petition for a writ of certiorari was dismissed (App. A, *infra*, 5a-6a).

C. The Decision After Remand

The Court of Customs and Patent Appeals reaffirmed its earlier judgments in both cases (App. A, *infra*, 40a, 70a).⁸ The majority discussed *Parker v. Flook*, *supra*, which it distinguished as being "concerned only with the question of what is a 'process' under § 101", an issue unrelated to the appeals before it (App. A, *infra*, 22a). It nevertheless asserted that *Flook* contained "an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated" (*id.* at 10a), and adopted a "novel * * * doctrine" with "potential for great harm to the incentives of the patent system" (*id.* at 23a-24a).⁹ The Court of Customs and Patent Appeals summarized: "[t]o conclude on the light *Flook* sheds on these cases, very simply * * * we find none" (*id.* at 26a). It therefore adhered both to the analysis and the conclusion in its earlier decisions, emphasizing that the plain language of Section 101 does not distinguish between living and inanimate matter (*id.* at 44a-45a, 64a-65a, 69a), and that considerations of novelty are unrelated to the

⁸The court, though not formally consolidating the cases, heard and decided them together because they involved "the same single question of law" (App. A, *infra*, 2a).

⁹The Court of Customs and Patent Appeals implied that the reason for the errors it perceived in *Flook* was that the briefs filed by the Solicitor General "badly, and with a seeming sense of purpose, confuse" the analysis of the Patent Act (*id.* at 17a).

determination of coverage under Section 101 (*id.* at 13a).¹⁰

Judge Miller, dissenting, stated that the majority had read *Parker v. Flook*, *supra*, too narrowly. He interpreted the decision in *Flook* as requiring a clear and certain signal from Congress where there is substantial doubt over Congress' intent to include a particular development as patentable subject matter under Section 101. From his reading of the legislative history of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, Judge Miller found that at least a substantial doubt existed about Congress' intent to include living things within the scope of patentable subject matter in Section 101 (App. A, *infra*, 96a).

REASONS FOR GRANTING THE WRIT

In concluding that living things are patentable subject matter under 35 U.S.C. 101, the Court of Customs and Patent Appeals significantly extended the coverage of the patent laws without legislative authorization, and rejected the principles of construction of the patent law recently restated in *Parker v. Flook*, 437 U.S. 584 (1978).

1. As the court below recognized, this decision is the first to hold that living things may themselves be patentable under 35 U.S.C. 101 (App. A, *infra*, 25a, 68a).¹¹ The economic implications of that holding are

¹⁰In a separate concurrence, Judge Baldwin found that the precedents cited in *Parker v. Flook* defined an area where patents were not possible because "the inventor attempted to preclude others from using those bare [natural] phenomena" (App. A, *infra*, 88a). He observed that in the instant cases the inventions did not "reach out to encompass natural phenomena * * *, but rather recite only non-naturally occurring compositions of matter that are but single tools for utilizing natural phenomena in producing new and useful end results" (App. A, *infra*, 91a).

¹¹Dicta in earlier cases, which the court below disapproved (App. A, *infra*, 45a-48a), suggest that living things are not patentable. See e.g. *Guaranty Trust Co. v. Union Solvents Corp.*,

very significant, given the vast area that it opens to patentability. Even if the holding applies only to microorganisms (compare App. A, *infra*, 45a with 48a-49a, 64a-67a), such basic life forms are among the most important areas of current research in the life sciences.¹² The decision below thus involves issues that clearly merit consideration by this Court. Moreover, review at this time is appropriate in order to avoid further complicating the already highly controversial policy problems surrounding genetic engineering¹³ with questions concerning the patentability of specific life forms.¹⁴

54 F. 2d 400, 410 (D. Del. 1931), *aff'd*, 61 F. 2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933); *Application of Mancy, et al.*, 499 F. 2d 1289, 1294 (C.C.P.A. 1974).

¹²Moreover, the nature of living things—especially microorganisms—creates a substantial risk that a patent monopoly will exceed its lawful limits. The difficulty of describing and understanding microorganisms creates serious problems in determining whether competitive developments are lawful or infringing. Cf. *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F. 2d 1347, 1379-1383 (5th Cir. 1976), *cert. denied*, 429 U.S. 1094 (1977); Jeffery, *The Patentability and Infringement of Sport Varieties: Chaos or Clarity?*, 59 J. Pat. Off. Soc'y 645, 654-657 (1977).

¹³See "Recombinant DNA Research: Revised Guidelines," released by the National Institutes of Health, 43 Fed. Reg. 60080, 60108, 60134 (1978). See also "Recombinant DNA: Accelerated Processing of Patent Applications for Inventions," 42 Fed. Reg. 2712-2713 (1977), suspended in part by "Recombinant DNA: Suspension of Accelerated Processing of Patent Applications for Recombinant DNA Research Inventions," 42 Fed. Reg. 13147 (1977).

¹⁴The decision of the court below, if unreviewed, means that the claimed patents will issue. But they may be held invalid if they are later challenged in a patent infringement suit in a district court. See 35 U.S.C. 281 *et seq.*, 28 U.S.C. 1338. The decision below thus does not finally resolve the issue of the patentability of living organisms. In light of the substantial economic interests involved, that issue can be expected to trouble the courts until resolved by this Court.

Only last Term this Court in *Parker v. Flook*, *supra*, held that the courts "must proceed cautiously when * * * asked to extend patent rights into areas wholly unforeseen by Congress." 437 U.S. at 596. The Court warned that when the expansion of patent rights is based on inference from ambiguous statutory language, it would "require a clear and certain signal from Congress * * * before approving the [patent]." *Ibid.* (quoting from *Deep South Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972)).¹⁵ This emphasis on caution was not new. *Flook* followed *Gottschalk v. Benson*, 409 U.S. 63, 72-73 (1972), where the Court emphasized that policy decisions concerning the extension of the patent laws to new fields are for Congress, not the courts. Thus, where such extensions are involved it is particularly important for the courts to interpret the patent laws so that "the prerequisites to obtaining a patent are strictly observed." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964).¹⁶

This Court's directive to reconsider *Bergy* in light of *Parker v. Flook* strongly underscored the lower court's obligation to be very careful before authorizing the grant of a patent. That court, however, concluded that the holding of *Parker v. Flook* was limited to the pat-

¹⁵The lower court found the quoted language inapplicable because the Court in *Deep South* was refusing a request that it modify prior cases interpreting the patent laws, and the requirement of a clear congressional signal was only applicable in those circumstances (App. A, *infra*, 24a-25a, 64a; but see 406 U.S. at 532). But the context of the quotation in *Flook* refutes that narrow reading; the Court used the quotation to summarize its concern over expanding patent protection into the "modern business of developing programs for computers," and concluded that whether or not such expansion was appropriate was for Congress, not the Court (437 U.S. at 595). The same reasoning applies to the even newer field of genetic engineering (see App. A, *infra*, 29a-30a).

¹⁶In *Stiffel*, this Court held that even a State's concern with unfair competition could not prevail over the exclusive responsibility of Congress to determine the extent of the patent laws.

entability of a "method of calculation," obviously not at issue here, and that its language "very simply" shed no light on the issues in these cases (App. A, *infra*, 26a). Accordingly, the Court of Customs and Patent Appeals reasserted its earlier interpretation of Section 101, emphasizing that the plain language of Section 101 is "broad and general," and requires no showing of novelty or inventiveness (App. A, *infra*, 12a-13a, 17a, 41a-42a, 69a). Its approach is inconsistent with that of the Court in *Flook*, and mirrors the analysis of the dissenting opinion in that case (437 U.S. at 600), which, like the court below, criticizes the majority for "importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness."¹⁷

In contrast, the Court in *Flook* noted that "a purely literal reading of" Section 101 is inconsistent with this Court's cases (437 U.S. at 588-589), and rejected the argument that its approach "improperly imports into § 101 the considerations of 'inventiveness' which are the proper concerns of §§ 102 and 103" (*id.* at 592). Instead, the Court emphasized, "The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kinds of 'discoveries' that the statute was enacted to protect" (*id.* at 592-593). Living things—whether naturally occurring, isolated, or genetically engineered—are no more "discoveries" of the kind the statute was enacted to protect than are the mathematical principles involved in *Flook*. And, as the Court's analysis in *Flook* makes clear, it is unnecessary to consider whether such "discoveries" meet the novelty and inventiveness requirements of Sections 102

¹⁷This inconsistency between the analysis of the scope of Section 101 in *Flook* and in the decision below, which can only create uncertainty in the administration of the patent laws, is an additional reason why review by the Court is warranted.

and 103 in order to deny them patentability—they are simply outside the scope of the general patent laws.

2. The question is thus whether Congress intended to include living things within the scope of the general patent laws. We submit that it did not. Instead, when it believed that it was appropriate to extend patent protection to particular types of living things, it developed special statutory provisions to do so, and imposed the particular requirements it considered appropriate in the circumstances.

In 1930, Congress enacted the Plant Patent Act, 35 U.S.C. 161 *et seq.*, to afford patent protection to certain kinds of asexually-reproduced plants. Congress evidently believed that existing patent law did not extend to living things, for if plants, as living things, already were patentable under Section 101, there would have been no need to provide specifically for plant patents. The legislative history of the 1930 Act confirms that Congress intended for the first time to extend patent protection beyond its previous limits. Both the House and Senate committees considering the bill reported that:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry * * *. The bill will remove the existing discrimination between plant developers and industrial inventors. [H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930)].¹⁸

¹⁸ Appended to both the House and Senate Reports were letters from then Secretary of Agriculture Hyde, referring more specifically to the coverage of the pre-existing patent law:

The evident purpose of the bill is to encourage the improvement of some kinds of cultivated plants * * *. This purpose is sought to be accomplished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inani-

Forty years later, Congress again evidenced its belief that living organisms were not covered by 35 U.S.C. 101, and that to afford them protection separate legislation was needed. The Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542, 7 U.S.C. 2321 *et. seq.*, gave the Secretary of Agriculture authority to issue certificates of Plant Variety Protection, similar to patents, for new varieties of sexually-reproduced plants (Section 51, 7 U.S.C. 2421). Significantly, the statute expressly provides that bacteria and fungi are not entitled to protection (Section 42, 7 U.S.C. 2402).¹⁹

Again, the legislative history of the Act unmistakably indicates that Congress was extending protection to materials not previously covered under the patent laws—*i.e.*, materials that were not within the terms of either the 1930 Act or 35 U.S.C. 101. Thus, the House Report states (H.R. Rep. No. 91-1605, 91st Cong., 2d Sess. 1 (1970)):

Under patent law, protection is presently limited to those varieties of plants which reproduce asexually * * *. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of

mate nature. [H.R. Rep. No. 1129, 71st Cong., 2d Sess. 10 (Appendix A) (1930); S. Rep. No. 315, 71st cong., 2d Sess. 9 (Appendix A) (1930).]

¹⁹ In *In re Arzberger*, 112 F.2d 834, 837 (C.C.P.A. 1940), the court had earlier recognized that "the characteristics of plants predominate in bacteria, and bacteria are usually scientifically classified as plants." The court nevertheless affirmed the Board's refusal to issue a plant patent for certain bacteria. Nothing in *Arzberger* implies that the bacteria could have been patented under the general patent laws. Instead, the court quoted with approval the examiner's statement that the Plant Patent Act was not designed "to afford patent protection for bacteria used in the production of butyl alcohol, ethyl alcohol, and acetone" (112 F.2d at 836), suggesting that no such protection was otherwise available.

the economically important agricultural crops, such as cotton or soybeans.

The Court of Customs and Patent Appeals strained to avoid the force of this legislative history. Its principal argument was that the history should be ignored as a matter of law, for it "ascribe[s] to a preceding Congress an intent that the members of that Congress did not themselves state" (App. A, *infra*, 51a). It hardly advances the careful search for congressional intent, however, to make rote application of general maxims, and no useful source of legislative history should be reflexively cast aside. Cf. *Train v. Colorado Public Interest Research Group*, 426 U.S. 1, 10 (1976). The views of the Congress that passed the Plant Patent Act concerning Section 101's applicability to living things deserve especially serious consideration where, as here, the terms of the general statute hardly define themselves. *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-381 (1969); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 274-275 (1974). In any event, Congress in revising and codifying the patent code in 1952 chose to maintain explicitly the distinction among living things that the Plant Patent Act effects.

The lower court also contended that the Plant Patent Act itself shows that Congress did not consider it important that plants are living things. It read the Act as intended primarily to extend the patent system to a nonindustrial area, plant breeding, and secondarily to reject the judicial interpretation of the patent code that plants of the sort created by plant breeders like Luther Burbank were nonetheless "products of nature" and, as such, non-statutory subject matter (App. A, *infra*, 56a-59a). The first stated objective, however, necessarily assumes that Congress believed that Section 101 would not, without special amendment, apply to living things.²⁰ The second stated objective is not supported

²⁰ Because the general patent statute has from the beginning been applied to agricultural as well as industrial uses, it is ex-

by the legislative history of the Act. There is nothing in that history to indicate that Congress viewed plants developed by breeders like Burbank as already patentable subject matter but for decisions holding them outside the patent statutes as "products of nature."²¹

Finally, the Court of Customs and Patent Appeals evidently thought that it is illogical not to allow patents on living things themselves while allowing patents on processes that use living things (App. A, *infra*, 44a-45a, 49a, 67a-68a). This is not so, however. This Court has long recognized that an entity not itself patentable subject matter may nonetheless be used in a patentable process. See *Parker v. Flook*, *supra*, 437 U.S. at 588-592. Just as there is nothing illogical in holding that Congress did not give patent protection to a mathematical formula itself but allowed it on certain processes which exploit that formula, there is nothing illogical in a congressional intent to deny patents on living things themselves yet to allow patents on processes which use them, or, in appropriate circumstances, on processes to isolate or produce them.

ceedingly unlikely that Congress believed that Section 101 provided for only industrial patents, and that the new Act was necessary to provide patent protection simply because of the agricultural character of the discoveries involved.

²¹ The legislative history of the Plant Patent Act contains no evidence of congressional awareness of *Ex Parte Latimer*, 1889 C.D. 123, cited by the court below as the interpretation of the general patent law that the Act was designed to overcome (App. A, *infra*, 59a-61a).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APPENDIX A

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Appeal No. 76-712

Serial No. 477,766

IN THE MATTER OF THE APPLICATION OF

MALCOLM E. BERGY, JOHN H. COATS,
and VEDPAL S. MALIK

Appeal No. 77-535

Serial No. 260,563

IN THE MATTER OF THE APPLICATION OF

ANANDA M. CHAKRABARTY

DECIDED: MARCH 29, 1979

Before MARKEY, Chief Judge, RICH, BALDWIN, LANE,
and MILLER, *Associate Judges*.

RICH, Judge.

Introduction

These appeals are from decisions of the Board of Appeals (board) of the United States Patent and Trademark Office (PTO) under 35 USC 141 by dissatisfied applicants for patents. We reverse.

These two cases come before us for the second time under the circumstances hereinafter detailed. Since our first decisions, they have been to the United States Supreme Court and back without any decision by that Court. They are separate appeals, not formally consolidated, but on this second round they were heard together on November 6, 1978, and are now decided together because, as will appear, they involve only the same single question of law.

The question before us is a limited one of statutory construction, not whether appellants have made and disclosed *patentable* inventions. The PTO has already determined that both applicants are entitled to patents; in technical patent law terms, unappealed claims to their respective inventions have been allowed to each appellant and, whatever the final disposition of these appeals, patents will issue if the applicants choose to pay their fees and take them out. Thus, there is no question of this court having "extended" the scope of the patent laws" as the *Bergy* petition for certiorari asserted (p. 6). Deciding a case of first impression is not necessarily an "extension" of the law, it is a determination of what it means.

The real question before us is whether appellants are to be allowed to define their inventions—already determined to be patentable—in a certain way in "claims" pursuant to 35 USC 112, second paragraph.¹ This ques-

¹ Insofar as applicable, §112 reads:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

tion, which is the same in each case, involves the construction and application of 35 USC 101, more particularly the meaning to be given to the words "manufacture" and "composition of matter" in that section, which reads:

Whoever invents or discovers any new and useful process, machine, *manufacture*, or *composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. [Emphasis ours.]

The PTO has raised no issue in either case, as to any aspect of the inventions, about compliance with the "conditions and requirements of this title," that is to say the basic Title 35 requirements for patentability, which are utility, novelty, and nonobviousness (35 USC 101, 102, and 103), or any other statutory condition or requirement such as adequacy of disclosure (35 USC 112, first paragraph). The sole issue, as the PTO chooses to view it, is whether an invention, otherwise patentable under the statute, is excluded from the categories of subject matter which may be patented, set forth in §101, because it is "alive." As we shall show, the PTO does not appear to us to have been altogether consistent in its position on this question. First, however, we review the history of this litigation to show the posture of the cases as they are now before us again.

Procedural Background

In re Bergy, 563 F.2d 1031, 195 USPQ 344 (CCPA 1977), *vacated sub nom. Parker v. Bergy*, 438 U.S. 932 (June 26, 1978), 198 USPQ 257 (1978), hereinafter "*Bergy*," was decided by us October 6, 1977. We reversed a 2-to-1 decision of the board, 197 USPQ 78 (Bd. App. 1976), which affirmed the final rejection by the PTO examiner of claim 5 of Bergy's application for pat-

ent serial No. 477,766, filed June 10, 1974.

The real party in interest in *Bergy* is the assignee of the application, the Upjohn Company, Kalamazoo, Michigan.

In re Chakrabarty, 571 F.2d 40, 197 USPQ 72 (CCPA), cert. dismissed, 47 U.S. L.W. 3129 (Aug. 25, 1978), hereinafter "*Chakrabarty*," was decided by us March 2, 1978. We reversed the decision of the board (unreported) which affirmed the final rejection by the PTO examiner of claims 7-9, 13, 15, 17, 21, and 24-26 of Chakrabarty's application for patent serial No. 260,563, filed June 7, 1972.

The real party in interest in *Chakrabarty* is the assignee of the application, General Electric Company.

In the PTO, *Chakrabarty* was the first of the two cases to be decided, the decision of the board being dated May 20, 1976. An entirely different panel of the board decided *Bergy* on June 22, 1976, one member dissenting with an extensive opinion. A long passage of the *Chakrabarty* board opinion was copied verbatim by the *Bergy* board majority. Due to delay caused by a request for reconsideration in the PTO in *Chakrabarty*, the *Bergy* appeal was the first to reach this court.

Having decided the sole question involved in *Bergy*, by our opinion dated October 6, 1977, when the identical question was presented to us in *Chakrabarty* in December of that year, we decided it on the basis of our *Bergy* decision as a controlling precedent in this court. Our opinion in *Chakrabarty* was published March 2, 1978.

On April 20, 1978, a petition for a writ of certiorari in *Bergy* was filed in the Supreme Court by the Solicitor General on behalf of Lutrelle F. Parker, Acting Commissioner of Patents and Trademarks. The Court granted the petition June 26, 1978, and on the same day issued the following order:

THIS CAUSE having been submitted on the petition for writ of certiorari and response thereto,

ON CONSIDERATION WHEREOF, it is ordered and adjudged by this Court that the judgment of the United States Court of Customs and Patent Appeals in this cause is vacated; and that this cause is remanded to the United States Court of Customs and Patent Appeals for further consideration in light of *Parker v. Flook*, 437 U.S. 584 (1978). [198 USPQ 193]

Parker v. Flook, 437 U.S. 584, 198 USPQ 193 (1978), hereinafter "*Flook*", was a case from this court (*In re Flook*, 559 F.2d 21, 195 USPQ 9 (CCPA 1977), reversed sub nom. *Parker v. Flook*, supra), involving a computerized method of updating alarm limits by application of a mathematical formula. It was decided by the Supreme Court, three Justices dissenting, on June 22, 1978, four days before the date of the foregoing order in *Bergy*.

Meanwhile, in *Chakrabarty*, an extension of time to file a petition for a writ of certiorari requested by the Solicitor General had been granted by the Chief Justice on May 26, 1978, extending the time to July 30, 1978. The petition No. 78-145, was filed on July 26, 1978.

August 3, 1978, the Commissioner of Patents and Trademarks, by his solicitor, petitioned this court to vacate its decision in *Chakrabarty*, recall its mandate, and enter a new decision affirming the PTO board in view of the Supreme Court's order in *Bergy*. The solicitor argued that the action taken in *Parker v. Flook* showed that our decision in *Chakrabarty* "was demonstrably wrong." Chakrabarty, on August 11, opposed the petition, pointing out that in the Supreme Court's order in *Bergy* "there is no hint that this Court's decisions in *Bergy* and *Chakrabarty* were 'demonstrably wrong'." We granted the petition to the extent of vacating our judgment.

Perceiving the foregoing situation and being mindful of the similarities as well as the differences of the *Bergy* and *Chakrabarty* cases and of the fact they involved the same single issue, we issued orders in *Bergy*

on August 8 and in *Chakrabarty* on August 11, 1978, restoring both cases to the calendar, setting times for filing supplementary briefs directed solely to the effect, if any, of *Parker v. Flook* on our decisions, and setting the cases for hearing together on November 6, 1978.

Counsel for *Chakrabarty* and the Solicitor General then stipulated, pursuant to Rule 60(1) of the Supreme Court, that *Chakrabarty's* petition for a writ of certiorari be dismissed in view of this court's order vacating our judgment and recalling our mandate, and the petition was so dismissed on August 25, 1978.

Prior to the oral argument, this court received amicus curiae briefs on behalf of The Regents of the University of California, The American Patent Law Association, Genentech, Inc. (a California Corporation located in South San Francisco), and Cornell D. Cornish, patent attorney, on behalf of himself and the Village of Belle Terre, Long Island, New York.

The Genentech brief, furthermore, called to our attention three resolutions, Nos. 30-32, adopted by the Section of Patent, Trademark and Copyright Law of the American Bar Association at its August 1978 Annual meeting directed to the issue in these appeals and supportive of our prior decisions herein. (1978 Summary of Proceedings, Section of Patent, Trademark and Copyright Law, A.B.A. 31.)

Appellants in both cases and the PTO appeared by counsel on November 6, 1978, and presented oral argument, whereupon the appeals were resubmitted for new decisions.

Present Posture of the Cases Summarized

In *Bergy* our judgment of October 6, 1977, was vacated by the Supreme Court on certiorari and we were directed to reconsider the case in the light of *Flook*. In *Chakrabarty*, because the identical issue was involved, we vacated our own March 2, 1978, decision at the request of the PTO because it was obviously necessary to

give it the same reconsideration. We therefore approach both cases with the slate wiped clean, having been "returned to square one," to use a board game expression. Whatever we have to say in these cases is said here, though much of it was said before, and our prior opinions are to be deemed withdrawn. While certiorari was granted in *Bergy*, that case was returned to us without having been briefed or argued before the Supreme Court, on the very day that certiorari was granted, at the end of the Court's term, and within four days of the decision in *Flook*, to be reconsidered by us in the light of the High Court's opinion in *Flook*. The Court gave no intimation of what bearing it thought *Flook* has on the single issue in these appeals, except as it may be gleaned from the *Flook* opinion.

Clearly, our assigned task is first to determine the bearing of *Flook*, if any, on these two appeals. This requires, as we see it, consideration not only of what was decided in *Flook* but examination of everything that was said in the opinion. Preliminary to that consideration, however, and laying the groundwork therefor, we will examine the Constitutional basis for the patent system and the anatomy of the statutes Congress has enacted insofar as they are relevant to the problem before us.

The Constitution

The grant of power to Congress to establish a patent system is in these familiar words of Article I, section 8, clauses 8 and 18:

The Congress shall have power * * * [8] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; * * * And

[18] To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers * * * .

Scholars who have studied this provision, its origins, and its subsequent history, have, from time to time, pointed out that it is really two grants of power rolled into one; first, to establish a copyright system and, second, to establish a patent system. See R. DeWolf, *An Outline of Copyright Law* 15 (1925); K. Lutz, *Patents and Science. A Clarification of the Patent Clause of the Constitution*, 18 Geo. Wash. L. Rev. 50 (1949); P. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. §1 to §110, 1, 3 (1954); G. Rich, *Principles of Patentability*, 28 Geo. Wash., L. Rev. 393 (1960). Their conclusions have been that the constitutionally-stated purpose of granting patent rights to inventors for their discoveries is the promotion of progress in the "useful Arts," rather than in science. In enacting the 1952 Patent Act, both houses of Congress adopted in their reports this construction of the Constitution in identical words, as follows:

The background, the balanced construction, and the usage current then and later, indicate that the constitutional provision is really two provisions merged into one. The purpose of the first provision is to promote the progress of *science* by securing for limited time to *authors* the exclusive right to their *writings*, the word "science" in this connection having the meaning of knowledge in general, which is one of its meanings today. The other provision is that Congress has the power to promote the *progress of useful arts* by securing for limited times to *inventors* the exclusive right to their *discoveries*. The first patent law and all patent laws up to a much later period were entitled "Acts to promote the progress of useful arts." [H.R. Rep. No. 1923, 82d Cong., 2d Sess. 4 (1952); S. Rep. No. 1979, 82 Cong., 2d Sess. 3 (1952). Emphasis ours.]

It is to be observed that the Constitutional clause under consideration neither gave to nor preserved in inventors (or authors) any rights and set no standards

for the patentability² of individual inventions; it merely empowered Congress, if it elected to do so, to secure to inventors an "exclusive right"³ for an unstated "limited" time for the stated purpose of promoting useful arts. We have previously pointed out that the present day equivalent of the term "useful arts" employed by the Founding Fathers is "technological arts." *In re Musgrave*, 57 CCPA 1352, 1367, 431 F.2d 882, 893, 167

²We use the term "patentability" although the Constitution does not mention patents because history shows that the authors of the Constitution had patents in mind as the means for securing exclusive rights to inventors. They had been in use in the American colonies and the practice had been imported from England. See B. Bugbee, *The Genesis of American Patent and Copyright Law*, Chap. VI (1967). The only restraints placed on Congress pertained to the *means* by which it could promote useful arts, namely, through the device of securing "exclusive rights" which were required to be limited in time, a device known to governments for centuries. The conditions to be imposed on the granting of such rights, which have varied through the years, were left to Congress to devise. *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966).

³The term "exclusive right" is one which caused much confusion in thinking throughout much of the early history of patent law, at least until 1852 when the Supreme Court decided *Bloomer v. McQuewan*, 55 U.S. 539, wherein it pointed out (p. 548) that

The franchise which the patent grants, consists altogether in the *right to exclude* everyone from making, using, or vending the thing patented, without the permission of the patentee. *This is all that he obtains by the patent.* [Emphasis ours.]

Confusion persisted, however, principally for the reason that until 1952 the patent statute phrased the patent grant, Revised Statutes §4883, as "the *exclusive right* to make, use, and vend the invention * * *." [Emphasis ours.] The patent grant never has had anything to do with the patentee's right to make, use, or vend, and the 1952 Act clarified the right to conform to *Bloomer v. McQuewan*. 35 USC 154.

USPQ 280, 289-90 (1970). See also *In re Waldbaum*, 59 CCPA 940, 457 F.2d 997, 173 USPQ 430 (1972) (Rich, J., concurring).

We turn now to a consideration of how Congress has implemented the power delegated to it.

Anatomy of the Patent Statute

The reason for our consideration of the statutory scheme in relation to its Constitutional purpose is that we have been directed to review our prior decisions in the light of *Flook* and we find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *categories* of inventions in §101 which *may* be patentable and to the *conditions* for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of §103. The confusion creeps in through such phrases as "eligible for patent protection," "patentable process," "new and useful," "inventive application," "inventive concept," and "patentable invention." The last mentioned term is perhaps one of the most difficult to deal with unless it is used *exclusively* with reference to an invention which complies with *every* condition of the patent statutes so that a valid patent may be issued on it.

The problem of accurate, unambiguous expression is exacerbated by the fact that prior to the Patent Act of 1952 the words "invention," "inventive," and "invent" had distinct legal implications related to the concept of patentability which they have not had for the past quarter century. Prior to 1952, and for sometime thereafter, they were used by courts as imputing *patentability*. Statements in the older cases must be handled with care lest the terms used in their reasoning clash with the reformed terminology of the present statute; lack of meticulous care may lead to distorted legal conclusions.

The transition made in 1952 was with respect to the

old term "invention," imputing *patentability*, which term was replaced by a new statutory provision, §103, requiring *nonobviousness*, as is well explained and approved in *Graham v. John Deere Co.*, supra n. 2. Part IV of that opinion, entitled "The 1952 Act," quotes the key sections of the statute upon which patentability depends. *Graham* states that there are three explicit conditions, novelty, utility, and nonobviousness, which is true, but there is a fourth requirement, which, alone, is involved here. This was also the sole requirement involved in *Flook*.

The Revised Statutes of 1874, which contained the primary patent statutes revised and codified in 1952, lumped most of the conditions for patentability in a single section, §4886, as did all of the prior statutes back to the first one of 1790. The 1952 Act divided that statute up into its logical components and *added* the nonobviousness requirement, which until then had been imposed only by court decisions. This attempt at a clearcut statement to replace what had been a hodgepodge of separate enactments resulted in a new and official Title 35 in the United States Code with three main divisions. Part I pertains to the establishment and organization of the PTO. Part II, here involved, covers patentability of inventions and the grant of patents. Part III relates to issued patents and the protection of the rights conferred by them.

All of the statutory law relevant to the present cases is found in four of the five sections in Chapter 10, the first chapter of Part II:

- Sec. 100 Definitions
- Sec. 101 Inventions patentable [if they qualify]
- Sec. 102 Conditions for patentability; novelty and loss of right to patent
- Sec. 103 Conditions for patentability; non-obvious subject matter

More strictly speaking, these cases involve only §101, as did *Flook*. Achieving the ultimate goal of a patent

under those statutory provisions involves, to use an analogy, having the separate keys to open in succession the three doors of sections 101, 102, and 103, the last two guarding the public interest by assuring that patents are not granted which would take from the public that which it already enjoys (matters already within its knowledge whether in actual use or not) or *potentially* enjoys by reason of obviousness from knowledge which it already has.

Inventors of patentable inventions, as a class, are those who bridge the chasm between the known and the obvious on the one side and that which promotes progress in useful arts or technology on the other.

The first door which must be opened on the difficult path to patentability is §101 (augmented by the §100 definitions), quoted *supra* p. 3.⁴ The person approaching that door is *an inventor*, whether his invention is patentable or not. There is always an inventor; being an inventor might be regarded as a preliminary legal requirement, for if he has not invented something, if he comes with something he knows was invented by someone else, he has no right even to approach the door. Thus, section 101 begins with the words "Whoever invents or discovers," and since 1790 the patent statutes have always said substantially that. Being an inventor or having an invention, however, is no guarantee of opening even the first door. What *kind* of an invention or discovery is it? In dealing with the question of kind, as distinguished from the qualitative conditions which make the invention patentable, §101 is broad and general; its language is: "any * * * process, machine, manufacture, or composition of matter, or any * * * improvement thereof." Section 100(b) further expands "process" to include "art or method, and * * * a new use

⁴The Supreme Court has directed that the determination that statutory subject matter under §101 exists "must precede" the inquiries under §§102-103. *Parker v. Flook*, *supra*, 438 U.S. at 593, 198 USPQ at 198-199.

of a known process, machine, manufacture, composition of matter, or material." If the invention, as the inventor defines it in his claims (pursuant to §112, second paragraph), falls into any one of the named categories, he is allowed to pass through to the second door, which is §102; "novelty and loss of right to patent" is the sign on it. Notwithstanding the words "new and useful" in §101, the invention is not examined under that statute for novelty because that is not the statutory scheme of things or the long-established administrative practice.

Section 101 *states* three requirements: novelty, utility, and statutory subject matter. The understanding that these three requirements are *separate and distinct* is long-standing and has been universally accepted. The text writers are all in accord and treat these requirements under separate chapters and headings. See, e.g., *Curtis's Law of Patents*, Chapters I and II (1873); 1 *Robinson on Patents* §§69-70 at 105-109 (1890); 1 *Rogers on Patents* (1914); *Revisé & Caesar, Patentability and Validity*, Chapters II, III, IV (1936); *Deller's Walker on Patents*, chapters II, IV, V (1964). Thus, the questions of whether a particular invention is *novel* or *useful* are questions wholly apart from whether the invention falls into a category of *statutory subject matter*. Of the three requirements *stated* in §101, only two, utility and statutory subject matter, are *applied* under §101. As we shall show, in 1952 Congress voiced its intent to consider the novelty of an invention under §102 where it is first made clear what the statute means by "new", notwithstanding the fact that this requirement is first *named* in §101.

The PTO, in administering the patent laws, has, for the most part, consistently applied §102 in making rejections for lack of novelty. To provide the option of making such a rejection under either §101 or §102 is confusing and therefore bad law. Our research has disclosed only two instances in which rejections for lack of novelty were made by the PTO under §101, *In re Bergstrom*, 57 CCPA 1240, 427 F.2d 1394, 166 USPQ

256 (1970); *In re Seaborg*, 51 CCPA 1109, 328 F.2d 996, 140 USPQ 662 (1964). In *In re Bergstrom* we in effect treated the rejection as if it had been made under §102, observing in the process that "The word 'new' in §101 is to be construed in accordance with the provisions of §102." 57 CCPA at 1249, 427 F.2d at 1401, 166 USPQ at 262.

When §101 was enacted, the accompanying Reviser's Note stated (inserts and emphasis ours):

The corresponding section of the existing statute [R.S. §4886] is split into two sections, section 101 relating to the *subject matter* for which patents *may* be obtained ["subject to the conditions and requirements of this title"], and section 102 defining statutory novelty and stating other conditions for patentability.

H.R. Rep. No. 1923, *supra* at 6, another contemporaneous document, states (emphasis ours):

Part II relates to patentability of inventions and the grant of patents.

Referring first to section 101, this section specifies *the type of material* which can be the subject matter of a patent.

* * * * *

Section 101 sets forth the *subject matter* that can be patented "subject to the conditions and requirements of this title." *The conditions* under which a patent may be obtained *follow*, and section 102 covers the conditions relating to novelty.

A person may have "invented" a machine or a manufacture, which may include anything under the sun that is made by man, *but it is not necessarily patentable* under section 101 unless the conditions of the title are fulfilled.

Section 102 in paragraphs (a), (b), and (c) repeats the conditions in the existing law relating to novelty.

The Senate report, No. 1979, makes the identical statement.

The second door then, as we have already seen, is §102 pursuant to which the inventor's claims are examined for novelty, requiring, for the first time in the examination process, comparison with the prior art which, up to this point, has therefore been irrelevant.

Section 102 also contains other conditions under the heading "loss of right" which need not be considered here. An *invention* may be in a statutory category and not patentable for want of *novelty*, or it may be novel and still not be patentable because it must meet yet another condition existing in the law since 1850 when *Hotchkiss v. Greenwood*, 11 How. 248, was decided. This condition developed in the ensuing century into the "*requirement for invention*." See *Graham v. John Deere Co.*, *supra*.

The third door, under the 1952 Act, is §103 which was enacted *to take the place of the requirement for "invention."* We need not examine this requirement in detail for it is not involved in the present appeals, and was not involved in *Flook*. It will suffice to quote what the House and Senate reports, cited *supra*—"signals" from Congress—say about the third requirement, from which it will be seen that, again, the claimed invention for which a patent is sought must be compared with the prior art. We quote H.R. Rep. No. 1923, *supra* at 7:

Section 103, for the first time in our statute, provides a condition which exists in the law and has existed for more than 100 years, but only by reason of decisions of the courts. An *invention* which has been made, and which is new in the sense that the *same* thing has not been made [or known] before, may still not be patentable if the difference between the new thing and what was known before is not sufficiently great to warrant a patent. That has been expressed in a large variety of ways in decisions of the courts and in writings. Section 103 states this requirement in the title ["Conditions for patentability; non-obvious subject matter"]. It re-

fers to the difference between the subject matter sought to be patented *and the prior art*, meaning what was known before as described in section 102. If this difference is such that *the subject matter as a whole* would have been obvious at the time [the invention was made] to a person [ordinarily] skilled in the art, then the subject matter cannot be patented. [Insertions and emphasis ours.]

If the inventor holds the three different keys to the three doors, his *invention* (here assumed to be "useful") qualifies for a patent, otherwise not; but he, as *inventor*, must meet still other statutory requirements in the preparation and prosecution of his patent application. We need not here consider the latter because appellants have not been faulted by the PTO in their paperwork or behavior. The point not to be forgotten is that being an *inventor* and having made an *invention* is not changed by the fact that one or more or all of the conditions for *patentability* cannot be met. Year in and year out this court turns away the majority of the inventors who appeal here because their inventions do not qualify for patents. They remain inventions nevertheless. It is time to settle the point that the terms *invent*, *inventor*, *inventive*, and the like are unrelated to deciding whether the statutory requirements for patentability under the 1952 Act have been met. There is always an *invention*; the issue is its patentability. Terms like "inventive application" and "inventive concept" no longer have any useful place in deciding questions under the 1952 Act, notwithstanding their universal use in cases from the last century and the first half of this one. As Mr. Justice Holmes said in *Towne v. Eisner*, 245 U.S. 418, 425 (1918), "A word * * * may vary greatly in color and content according to the circumstances and the time in which it is used." And Mr. Justice Frankfurter said in *Shapiro v. United States*, 335 U.S. 1, 56 (1948), "It is the part of wisdom, particularly for judges, not to be victimized by words."

We have observed with regret that the briefs filed by the Solicitor General for Acting Commissioner Parker in *Parker v. Flook*, a case which, as the Court noted, "turns entirely on the proper construction of §101," badly, and with a seeming sense of purpose, confuse the statutory-categories requirement of §101 with a requirement for the existence of "invention." This they do by basing argument on the opening words of §101, "whoever invents or discovers," thereby importing into the discussion of compliance with §101 a requirement for "invention" in a patentability sense. But there has not been a requirement for "invention" in the patentability sense in the laws since 1952—the requirement was replaced by the §103 requirement for nonobviousness. *Graham v. John Deere Co.*, *supra*. Furthermore, when one has only compliance with §101 to consider, the sole question, aside from utility, is whether the invention falls into a named category, not whether it is *patentable*. Falling into a category does not involve considerations of novelty or nonobviousness and *only* those two considerations involve comparison with prior art or inquiry as to whether all or any part of the invention is or is not in, or assumed to be in, the prior art or the public domain. *Prior art is irrelevant to the determination of statutory subject matter under §101*. An invention can be statutory subject matter and be 100% old, devoid of any utility, or entirely obvious. This is our understanding of the statute and the basis on which we proceed to the further consideration of these appeals.

The error of the line of argument pursued in the Solicitor General's briefs in *Flook* is sufficiently illustrated by quoting from the summation of that argument in the opening paragraphs of the Reply Brief for the Petitioner, pages 1 and 2 (footnotes omitted, all emphasis and bracketed material in original):

1. Respondent errs in asserting (Br. 7-13) that our argument confuses the standard of non-obviousness prescribed in 35 U.S.C. §103 and the

requirement of statutory subject matter under 35 U.S.C. 101. As respondent recognizes, the patent examiner's sole ground for rejection of the claims at issue was that they did not cover statutory subject matter under 35 U.S.C. 101. We do not contend that respondent's particular algorithm for computing updated alarm-limits is not novel or is obvious within the meaning of 35 U.S.C. 102 or 103. We simply contend that the subject matter he seeks to patent is unpatentable under 35 U.S.C. 101, because it is not an "invent[ion] or discover[y]" within the meaning of that Section.

The plain language of Section 101 requires that the application of a mathematical algorithm involve invention or discovery for it to be patentable. It states that patents may issue only to one who "*invents or discovers any * * * process, machine, manufacture, or composition of matter*" (emphasis supplied). This language dates from the original Patent Act of 1790. In none of the subsequent amendments to the patent statute has Congress altered this basic requirement.

Yet respondent would have the courts ignore this explicit language and adopt a new rule that would allow patents to issue to anyone who "[*applies for a patent on*] any * * * process, machine, manufacture, or composition of matter, * * * subject to the conditions and requirements of this title". Congress could have changed the language of Section 101 to broaden the statutory standards of patentability, but it did not; indeed, respondent agrees (Br. 11) that in the 1952 Patent Act revision, Congress intended to codify the existing judicial precedents regarding the standard of patentability.

It is transparently clear that the above argument makes the opening words of §101, "Whoever invents or discovers," into a requirement for compliance with §103, the 1952 replacement for the old requirement for "invention"; one must get through the third door in

order to get past the first one! That is not the statutory scheme.⁵ The statement that respondent Flook was asking for a rule under which "anyone who [*applies for a patent on*] any * * * " of the §101 named categories should have a patent "issue" to him is subversive nonsense. There is no *issuance* without examination for novelty and nonobviousness. The statement that "Congress could have changed the language of section 101 to broaden the statutory standards of patentability, but it did not" is wholly beside the point because §101 was never intended to be a "standard of patentability"; the standards, or conditions as the statute calls them, are in §102 and §103. The naming of the categories of inventions that *may* be patented, in whatever statute appearing, has never supplied a standard. The question here, as it always has been, is: are the inventions claimed of a *kind* contemplated by Congress as possibly patentable *if* they turn out to be new, useful, and unobvious within the meaning of those terms as used in the statute.

For a better understanding of the issues presented by the present appeals, one further matter should be pointed out. An "invention" in the popular sense may have many aspects in the patent law sense and, technically speaking, may really be an aggregation of closely related inventions all pertaining to the same contribution the inventor is making to the technological arts. This will later be seen to be the case with the inven-

⁵ In our view, the opening phrase of §101, "Whoever invents or discovers," merely embodies the constitutional limitation in Article I, section 8, clause 8, that only the *person* who invents or discovers may be the beneficiary of the exercise of Congressional power and thus "obtain a patent * * * subject to the conditions and requirements of this title [Title 35 USC]." The plain meaning of the statute is that certain *persons* may obtain patents for certain enumerated *classes* of subject matter. Provisions are made elsewhere in Title 35 for applications by persons other than the true inventor, see §§111, 116-18. We find no support in the statute or its legislative history for any other interpretation.

tions of Bergy and Chakrabarty. When that is so, the applicant is in a position to define his invention(s) in claims (technical legal definitions of the spheres of *protection* sought, not *descriptions* of the invention) which may fall into different §101 categories. For example, an inventor may have produced a new product which is made by a new process and put to a new use. The invention is capable, therefore, of being defined or *claimed* as a manufacture or composition of matter, as a process for making the product, and as a process utilizing the product in some way. The PTO has procedures under which it may or may not permit claims of differing types to be prosecuted in the same patent application. In each of the cases here on appeal, the application contains claims of different types—to process and to product. In each application the process claims have been approved—stand “allowed”—only product claims being rejected and on appeal; but in each application all of the claims pertain to the *same invention*, considered broadly and in terms of the contribution of the inventor.

Before explaining the Bergy and Chakrabarty inventions, we shall state our understanding of the views expressed by the Supreme Court in the *Flook* opinion and the light shed thereby on the problems before us.

In light of Parker V. Flook

We are redeciding these appeals, as directed, “in light of *Parker v. Flook*.” The parties were given the opportunity in briefs and oral argument to tell us what bearing *Flook* has on these appeals. As might have been foreseen, the results are not helpful.

The PTO says the fact of remand should mandate affirmance and be “taken to buttress the positions taken by the dissenting judges.” The only specific thing seized upon, as a launching pad for argument, is a rhetorical passage quoted from *Deepsouth Packing Co. v. Littleton Corp.*, 406 U.S. 512, 531 (1972), about looking for a signal from Congress before *changing well-*

established law, a situation in no way involved here as will be discussed later. As everyone has conceded, we are dealing with appeals raising an issue of first impression in the courts, the effect on compliance with §101 of the fact of being “alive.”

Appellants and amici collectively tell us that *Flook* has no bearing, that it did not deal with the issue here, that we were right the first time, and that the reason for remand is unclear. In short, we can read more for ourselves than we have been told. We have read and analyzed *Flook* diligently.

The only thing we see in common in these appeals and in *Flook* is that they all involve §101. *Flook* was a review of one of the many appeals we have heard involving the general theme of the patentability of computer programs. The only way to claim a program is as a programmed “machine” or as a “process” or “method.” The *Flook* invention was claimed as a “process” under §101.⁶ That was the second case of its kind from this court reviewed by the Supreme Court, the first being *Gottschalk v. Benson*, 409 U.S. 63 (1972), which involved two method claims. Method and process claims are equivalents. *Flook* appears to have been decided on the authority of *Benson*. No method or process claim is here involved. In fact, the PTO has *allowed* (all three doors, §§101-2-3, passed) Bergy’s method claims 1 through 4 and Chakrabarty’s process claims 27 through 29, thereby holding that the process aspects of their in-

⁶The alternative claiming is as a “machine” under §101. *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976) was such a case but the §101 issue was not reached by the Court because it affirmed the rejection under §103, agreeing with the dissenting opinion of Chief Judge Markey. On the equivalence of process and machine claims in the software field and the application of §101 in that field, see *In re Johnston*, 502 F.2d 765, 772, 183 USPQ 172, 178 (CCPA 1974) (Rich, J., dissenting). For further discussion of the point, of the subject of claiming program inventions generally, and of the line of software cases up to January 1974, see J. Landis, *Mechanics of Patent Claim Drafting* 6, §41 88-102 (2d. ed. PLI 1974).

ventions are not only *subject matter* within §101 but also new and unobvious under §102 and §103, therefore patentable. *Flook* was concerned only with the question of what is a "process" under §101, in the context of computer program protection. No such issue is presented in either of these appeals.

There is no better authority on what the Supreme Court has decided in a case than the Court itself and we are fortunate to have its own summary of what it decided in *Flook*. It appears at the end of footnote 18, 437 U.S. at 595, as follows:

Very simply, our holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under §101.

We do not venture to elaborate. The appeals here involve no method of calculation, and the *Flook* holding appears to have no bearing.

As indicated earlier, we deem it our duty to seek whatever additional light there may be in the Court's opinion on the meaning of §101, without restricting ourselves to the holding. It is stated to be well established in patent law that the following are not within the statutory categories of subject matter enumerated in §101 and its predecessor statutes as interpreted through the years: principles, laws of nature, mental processes, intellectual concepts, ideas, natural phenomena, mathematical formulae, methods of calculation, fundamental truths, original causes, motives, the Pythagorean theorem, and the computer-implementable method claims of Benson and Tabbot. The present appeals do not involve an attempt to patent any of these things and the Court's review of this hornbook law is, therefore, inapplicable to the issue before us, which involves only the construction of the terms "manufacture, or composition of matter."

Another principle stated in *Flook* is that a "mathematical algorithm" or formula is like a law of na-

ture in that it is one of the "basic tools of scientific and technological work" and as such must be *deemed* to be "a familiar part of the prior art," even when it was not familiar, was not prior, was discovered by the applicant for patent, was novel at the time he discovered it, and was useful. This gives to the term "prior art," which is a *very* important term of art in patent law, particularly in the application of §103,⁷ an entirely new dimension with consequences of unforeseeable magnitude.

Insofar as the present appeals are concerned, the foregoing novel principle has no applicability whatever since, as we have said, no formula, algorithm, or law of nature is involved, and there has been no rejection on prior art of any kind in either application. In each, both the examiner and the Board of Appeals expressly stated that no references evidencing prior art have been relied on or applied.

Insofar as the general patent law is concerned, however, the above-stated novel *Flook* doctrine may have an unintended impact in putting an untimely and unjustifiable end to the long-standing proposition of law that

⁷Section 103 of Title 35 USC which makes nonobviousness of the invention a prerequisite to patentability requires a determination of "the differences between the subject matter sought to be patented and *the prior art*." (Emphasis ours.) Title 35 nowhere defines the term "prior art." Its exact meaning is a somewhat complex question of law which has been the subject of legal papers and whole chapters of books. See, for example, V. Woodcock, "What is Prior Art?" in *Dynamics of the Patent System* 263-332 (1960), and an enlarged version under the same title in *The Law of Chemical, Metallurgical and Pharmaceutical Patents* 87-215 (H. Forman, Ed., 1967). Basically, the concept of prior art is that which is publicly known, or at least known to someone who has taken steps which do make it known to the public, *cf.* 35 USC 102(e) and the case it codified, *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926), or known to the inventor against whose application it is being applied. See *In re Nomiya*, 509 F.2d 566, 184 USPQ 607 (CCPA 1975); *In re Bass*, 474 F.2d 1276, 177 USPQ 178 (CCPA 1973); *In re Hellsund*, 474 F.2d 1307, 177 USPQ 170 (CCPA 1973).

patentability may be predicated on discovering the cause of a problem even though, once that *cause* is known, the solution is brought about by obvious means. Such causes may often be classed as laws of nature or their effects. For examples, see *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 67-69 (1922); *In re Roberts*, 470 F.2d 1399, 176 USPQ 313 (CCPA 1973); *In re Conover*, 304 F.2d 680, 134 USPQ 238 (CCPA 1962). The potential for great harm to the incentives of the patent system is apparent.

It is one thing to say that a principle, natural cause, or formula, *per se*, is not within the categories of §101, but quite another to say it is "prior art" in determining the nonobviousness of an invention predicated on it even though the inventor discovered it.

One final matter with respect to *Flook* remains. In the PTO supplemental brief on remand, the solicitor places great emphasis on part of a passage which *Flook* quoted from the opinion of Mr. Justice White for the majority in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972):

We would require a clear and certain signal from Congress before approving the position of a litigant who, as respondent here, argues that the beach-head of privilege is wider, and the area of public use narrower, than the courts had previously thought. No such signal legitimizes respondent's position in this litigation.

While the solicitor believes that the entire opinion in *Flook* is relevant to the issue here, he says "the above quotation from *Deepsouth* reaches the heart of the matter."

We disagree. We cannot find in this passage any clear direction signal unless we wrench it out of the context in which it belongs and use it in a manner unwarranted by the situation which spawned it.

When we examine the portion of the paragraph in *Deepsouth* (also quoted in *Flook*) just preceding the solicitor-quoted passage, its meaning becomes clear. The Court stated: "It follows that we should not expand patent rights *by overruling or modifying our prior cases* construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language." (Emphasis ours.) The issue in *Deepsouth* was whether petitioner infringed by selling the unassembled parts of machines embodying patented combinations to foreign buyers who assembled and used them abroad. The relevant statutory provision, 35 USC 271, defines infringement by defining the infringer as anyone who "without authority *makes*, or sells any patented invention, *within the United States* during the term of the patent therefor * * * ." (Emphasis ours.) In deciding the case, the Court pointed out that a long line of judicial authority had established the meaning of the term "makes" contrary to the meaning urged by the respondent, with the result that the petitioner's sales of the parts to foreign buyers were not sales of "any patented invention" which was "made" in the United States, and, thus, were not acts of infringement. It is in this context that the Court made the quoted statement. The respondent in *Deepsouth* was asking the Court to expand established patent rights territorially, or to treat making parts of a machine as making the machine, by modifying prior cases construing the patent statutes. The Court refused, producing the quoted passage in the process.

We do not find the quoted passage to have any bearing on our problem. We are not faced with a litigant urging upon us a construction of §101 which is at odds with established precedent. Rather, we deal with a case of first impression. Not having been asked to make a change in existing law or to overrule or modify any case or to expand any right given by Congress, we need in this case no signal from that body.

To conclude on the light *Flook* sheds on these cases, very simply, for the reasons we have stated, we find none.

The Inventions of Bergy and Chakrabarty

1. Bergy, Coats, and Malik

These inventors, whom we collectively call "Bergy," provided the usual abstract in their patent application, which is a succinct statement of what they invented. It reads:

Microbiological process for preparing the antibiotic lincomycin at temperatures ranging from 18°C. to 45°C. using the newly discovered microorganism *Streptomyces vellosus*. The subject process advantageously results in the preparation of lincomycin without the concomitant production of lincomycin B (4'-depropyl-4'-ethylincomycin). The absence of lincomycin B production results in increased lincomycin recovery efficiency.

It is noted from this statement that Bergy invented a process for producing an old antibiotic and in the course of doing so discovered a previously unknown microorganism. The close relationship of the two inventions is apparent from the fact that it is this microorganism which, under the proper fermentation conditions, produces the antibiotic lincomycin, which had previously been produced from a different microorganism called *S. lincolnensis* and identified by the deposit number NRRL 2936. This former process was the subject of U.S. patent No. 3,086,912. The microorganism which Bergy discovered has the identifying number NRRL 8037. The application was filed with four claims to Bergy's process, all of which the examiner allowed. Claim 1, the only independent process claim, reads:

A novel process for preparing the antibiotic lincomycin which comprises cultivating *Streptomyces*

vellosus, having the identifying characteristics of NRRL 8037, and lincomycin-producing mutants thereof, in an aqueous nutrient medium under aerobic conditions until substantial antibiotic activity is imparted to said medium by the production of lincomycin.

As is obvious, that process is an industrial process in the pharmaceutical branch of the chemical industry and is performed by cultivating a living organism which produces the desired antibiotic. Were it not for the life process, nothing would happen. Since the process has been held to be patentable by the PTO, that claim and allowed claims 2, 3, and 4 dependent from it are not before us.

By a preliminary amendment, filed before the examiner acted on the application, appealed claim 5 was added together with the attorney's statement that "Basis for claim 5 can be found throughout the disclosure." Claim 5 reads:

A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

The designation "NRRL 8037" in the claims is elucidated by the following statement in the specification.

The Microorganism

The novel actinomycete used according to this invention for the production of lincomycin is *Streptomyces vellosus*. One of its strain characteristics is the production of lincomycin without the concomitant production of lincomycin B. Another of its strain characteristics is the production of comparable titers of lincomycin at a temperature of

28°C. and 45°C. A subculture of this living organism can be obtained upon request from the permanent collection of the Northern Regional Research Laboratories, Agricultural Research Services, U.S. Department of Agriculture, Peoria, Illinois, U.S.A. Its accession number in this repository is NRRL 8037.

The specification continues:

The microorganism of this invention was studied and characterized by Alma Dietz of the Upjohn Research Laboratory.

What follows that statement is an elaborate, highly technical, detailed description of the microorganism, including its type designation as "*Streptomyces vellosus* Dietz, sp.n.," occupying over ten pages of the printed specification, followed by exemplary descriptions of the production of lincomycin therefrom by fermentation processes and the recovery of the lincomycin produced by the fermentation.

A patent draftsman faced with the problem of obtaining protection for Bergy's invention necessarily had to begin with a determination of what Bergy had produced that is useful, new, and unobvious and what statutory category or categories it fits into. The problem was how to claim the invention. There were the usual options. Bergy's claim draftsman appears to have first determined that Bergy had invented a new and improved *process of making lincomycin* which could be conducted with advantage at higher temperatures so that less cooling was required and with the further advantage of less production of unwanted lincomycin B. The invention was, therefore, claimed as a process, as set forth in allowed claim 1, *supra*. It appears that further analysis by the claim draftsman of *what* was new and nonobvious about the process developed the insight that it was Bergy's development of the biologically pure culture of *Streptomyces vellosus*, the microorganism

which he discovered, the pure culture of which was the one thing which made the process possible. The process is the use of the culture; it is the microorganism culture which makes the lincomycin. Without the culture, the process does not exist. Bergy's invention might be said to "reside in" the culture which he made of the microorganism he discovered. Another way of defining his invention in a claim, therefore, was to define the culture, as claim 5 does. Bergy says the culture of claim 5 falls into either the "manufacture" or the "composition of matter" category of §101. It does not matter to our decision which it is as the PTO makes no differentiation. The PTO simply says it can be neither.

If, as the allowance of claim 1 indicates, Bergy's invention, when defined as a process, is patentable because it meets all of the requirements and conditions of the patent statutes, why is it not patentable when defined as in claim 5? That is the sole problem posed by Bergy's appeal. We shall return to it after we have explained the rejection.

2. Chakrabarty⁸

Chakrabarty's invention is in the relatively new and highly complex field of cellular or genetic engineering.

⁸ Ananda M. Chakrabarty, according to his declaration in the record, received a Ph.D. in biochemistry from Calcutta University in 1965, was a Post Doctoral Research Associate at the University of Illinois (Urbana) until 1971, and since then has been a Staff Microbiologist in the Research and Development Center of General Electric Company. At the time of the declaration, 1974, he had authored or co-authored some 25 technical papers in his field. According to the amicus brief of The Regents of the University of California (n. 11):

The pioneering character of the *Chakrabarty* invention in issue was specifically recognized in an article appearing in *National Geographic* vol. 150, pp. 355-395, at 374-5 and 383-4 (September 1976).

Further recognition of the significance of his invention appears in R. Cooke, *Improving on Nature*, at 152-63 (1977).

or microbial genetics. His specification is in such technical terms that it commences with the definition of some 17 terms. We shall refer only to 3 which seem necessary to give meaning to the claims we shall mention. Like Bergy's invention, Chakrabarty's is concerned with microorganisms. Unlike Bergy's, which manufactured antibiotics, Chakrabarty's were engineered to solve another one of man's practical needs, getting rid of oil spills. This they do by breaking down or "degrading" the components of the oil into simpler substances which serve as food for aquatic life whereby the oil, assumed to be floating on the sea, is absorbed into it.

Chakrabarty's invention is illustrated, with respect to its use, in connection with the degradation of crude oil and "Bunker C" oil, which are described as follows:

Crude oils, of course, vary greatly (depending upon source, period of activity of the well, etc.) in the relative amount of linear aliphatic, cyclic aliphatic, aromatic and polynuclear hydrocarbons present, although some of each of these classes of hydrocarbons is typically present in some amount in the chemical make up of all crude oils from producing wells.

* * * * *

Bunker C is (or is prepared from) the residuum remaining after the more commercially useful components have been removed from crude oil. This residuum is very thick and sticky and without significant use, per se.

Thus, "oil" is a mixture of several component hydrocarbon compounds and the ability to break down one component is not the ability to break down oil. Chakrabarty's specification gives the following explanation:

Microbial strains are known that can decompose individual components of crude oil (thus, various yeasts can degrade aliphatic straight-chain hydrocarbons, but not most of the aromatic and polynuclear hydrocarbons). *Pseudomonas* and

other bacteria species are known to degrade the aliphatic, aromatic and polynuclear aromatic hydrocarbon compounds, but, unfortunately any given strain can degrade only a particular component. For this reason, prior to the instant invention, biological control of oil spills had involved the use of a mixture of bacterial strains, each capable of degrading a single component of the oil complex [,] on the theory that the cumulative degradative actions would consumer the oil and convert it to cell mass. This cell mass in turn serves as food for aquatic life. However, since bacterial strains differ from one another in a) their rates of growth on the various hydrocarbon components, b) nutritional requirements, production of antibiotics or other toxic material, and c) requisite pH, temperature and mineral salts, the use of a mixed culture leads to the ultimate survival of but a portion of the initial collection of bacterial strains. As a result, when a mixed culture of hydrocarbon-degrading bacteria are deposited on an oil spill the bulk of the oil often remains unattacked for a long period of time (weeks) and is free to spread or sink.

In essence what Chakrabarty invented was new strains of *Pseudomonas* having the new capability within themselves of degrading several different components of oil with the result that degradation occurs more rapidly. This he did by transmission into a single bacterial cell of a plurality of compatible "plasmids," thereby creating the new strains. The specification discloses two such new strains on deposit with the Department of Agriculture's Northern Regional Research Laboratories, NRRL B-5472 and NRRL B-5473. Before proceeding further, we quote some of the definitions from the specification:

Extrachromosomal element . . . a hereditary unit that is physically separate from the chromosome of the cell; the terms "extrachromosomal element" and "plasmid" are synonymous; when physically separated from the chromosome, some plasmids

can be transmitted at high frequency to other cells, the transfer being without associated chromosomal transfer. [Second emphasis added.]

* * * *

Plasmids are believed to consist of double-stranded DNA [deoxyribonucleic acid] molecules. The genetic organization of a plasmid is believed to include at least one replication site and a maintenance site for attachment thereof to a structural component of the host cell.

* * * *

Degradative pathway . . . a sequence of enzymatic reactions (e.g. 5 to 10 enzymes are produced by the microbe) converting the primary substrate [i.e., oil] to some simple common metabolite, a normal food substance for microorganisms.

To create his new strains of microorganisms, Chakrabarty started with a strain of *Pseudomonas aeruginosa*, which itself exhibited no capacity for degrading any component of oil. By a unique process, the details of which we need not consider, he transferred four plasmids, having the individual capabilities for degrading n-octane (a linear aliphatic hydrocarbon), camphor (a cyclic aliphatic hydrocarbon), salicylate (an aromatic hydrocarbon), and naphthalene (a polynuclear hydrocarbon), into the *Pseudomonas aeruginosa* bacterium that previously had none of the plasmids in question. This resulted in a new strain having new capacities to produce numerous enzymes to degrade four main components of oil.

Chakrabarty thus describes how to use his new bacterium:

In practice an *inoculum* of dry (or lyophilized [freeze-dried]) powders of these genetically engineered microbes will be dispersed over (e.g. from overhead) an oil spill as soon as possible to control spreading of the oil. * * *. A particularly beneficial

manner of depositing the inoculum on the oil spill is to *impregnate straw with the inoculum* and drop the inoculated straw on the oil spill where both components will be put to use—the *inoculum* (mass of microbes) to degrade the oil and the *straw to act as a carrier* for the microbes and also to function as an oil absorbent. Other absorbent materials may be used, if desired, but straw is the most practical. [Emphasis ours.]

We turn now to the claiming of Chakrabarty's invention, hoping that the foregoing explanation of what he invented, though undoubtedly technically inadequate, is not too inaccurate and is sufficient to present clearly the legal issue. It is clear enough that the central core of the invention is a new strain or strains of bacteria, and that part of the invention is a process of combating oil spills. The patent draftsman presented four groups of claims; two groups have been rejected and two allowed, the former group being the claims on appeal. Claims of the first group, 7-9, 13, 15, 17 and 21, are directed to a bacterium. Claim 7 is the only independent claim and the others are dependent from it. Claim 7 reads:

7. A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.
[⁹]

The second group, 21 and 24-26, are directed to an inoculum, the only independent claim being 21 which reads:

21. An inoculum for the degradation of a pre-selected substrate comprising a complex or mixture

⁹As a matter of general interest, the assignee of appellant's invention has been granted British patent 1,436,573 containing this and other claims to the bacterium.

of hydrocarbons, said inoculum consisting essentially of bacteria of the genus *Pseudomonas* at least some of which contain at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

It will be noted that claims 7 and 21 are but alternative ways of claiming substantially the same thing since the inoculum consists essentially of the bacterium. As we saw earlier, the inoculum may be a dried preparation of the new bacteria in the form of a powder. These two groups of claims are under rejection as not being "manufactures" or "compositions of matter" within §101.

The third group consists of claims 27-29 directed to a process or improvement in a process of transferring plasmids from a donor to a recipient bacterium. The fourth group consists of claims 30-32, 35, and 36 directed to an inoculated medium, the only independent claim being claim 30 which reads:

30. An inoculated medium for the degradation of liquid hydrocarbon substrate material floating on water, said inoculated medium comprising a carrier material able to float on water and bacteria from the genus *Pseudomonas* carried thereby, at least some of said bacteria each containing at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway and said carrier material being able to absorb said hydrocarbon material.

These claims of the last two groups of claims have been held to be patentable by the PTO and have been allowed. Therefore, Chakrabarty will be able to have a patent on his invention as defined therein.

Comparison of claim 30 with rejected claims 7 and 21, *supra*, shows that it differs from them in substance only in adding to the bacterium of claim 7 or the inoculum of claim 21 a "carrier" which will float on water and absorb oil. As shown above, the preferred carrier is

straw. The significance of this is that the PTO obviously has no hesitation in issuing a patent on the living bacterium or inoculum when applied to or mixed with straw, which combination it must consider to be a manufacture or a composition of matter under §101, but refuses to issue a patent on the new bacterium or inoculum itself which is Chakrabarty's real contribution to the technological arts.

The Rejections

1. Chakrabarty

We take up Chakrabarty's application first because it was the first to be filed and the first to be decided by the PTO board, as we stated at the beginning of this opinion.

The PTO Board of Appeals *said* the examiner rejected the appealed claims as not within §101 for two reasons: (1) the claimed microorganisms are "products of nature" and (2) the claims "are drawn to live organisms." However, we do not find in the examiner's final rejection or Answer on the appeal any rejection other than (1). Rejection (2) appears to have been created in the board by misreading the Answer. In expressly reversing ground (1), the board said:

We agree with appellant that the claimed bacteria may not be considered as being "products of nature" simply because from the record we must conclude that *Pseudomonas* bacteria containing two or more different energy generating plasmids are not naturally occurring.

This left only ground (2), which the board sustained. In its opinion it said it had examined the cases cited by the examiner and appellant and others as well and had found "no case dealing directly with the point here in issue * * * ." It viewed the question before it as "whether living organisms (appellant's modified bac-

terium) are patentable subject matter under 35 U.S.C. 101." It next said, "We realize that 35 U.S.C. 101 does not expressly exclude patents on living organisms. * * * ." It then propounded the theory the PTO has pursued ever since to the effect that Congress could not have intended §101 to include *any* living thing because, if it had, Congress would not have found it necessary to pass the Plant Patent Act of 1930 (Pub. L. No. 245, 46 Stat. 376) which amended R.S. §4886, in order to provide protection for plants. The board reasoned that if plants, which are alive, were not thought by Congress to be within §101, then *nothing* alive is within it. Conversely, the board felt that if new species of bacteria were held to be within §101, then logically it would have to follow that *all* life forms would be, including the human species. It therefore sustained the rejection of the appealed claims on the sole ground that the bacteria covered thereby are "alive," basing its holding on its view of what Congress must have intended.

2. Bergy

When we first considered the *Bergy* board opinion we were not aware of the *Chakrabarty* board decision, which only came to our attention several months later. We now understand *why* the board opinion, which we formerly characterized as "quite out of the ordinary" because it disregarded the examiner's ground of rejection to the point of refusing to consider it, substituted for the examiner's ground its own view that appealed claim 5 was properly rejected because it covered a living organism. The *Bergy* board was adopting the *Chakrabarty* board's reasoning to the point of copying a large portion of it verbatim. It is therefore, in substance, the same decision.

The examiner's sole ground of rejection of Bergy's claim 5, as stated in his final rejection, was:

Claim 5 is rejected under 35 USC 101 as non-statutory subject matter. Claim 5 claims a *product*

of nature (*Streptomyces vellosus* NRRL 8037). See *In re Mancy et al.* 192 USPQ 303 at page 306, second sentence before [4]. [Emphasis ours.]

Bergy responded with a request to reconsider this rejection, supported by affidavits of three Upjohn microbiologists, Dr. Joseph E. Grady, Dr. Thomas L. Miller, and "the well-known microbial taxonomist Alma Dietz," pointing out that the microorganism did not exist as a biologically pure culture in nature and asserting that such a culture is a "manufacture" under §101, *supra*. In so arguing, Bergy made the point that the pure culture is "a product of a microbiologist." As bearing on the nature of Bergy's invention, we note what the affiants' main points were. Dr. Grady said:

The "biologically pure culture" of claim 5 is a well-defined product of the microbiologist which is capable of producing the desired antibiotic lincomycin under controlled fermentation conditions. In contrast, the soil source in which the microorganism was discovered is a complex microbial environment which, as such, could not be used to produce a desired product under any known fermentation conditions.

* * * * *

In summary, soil contains a complex jungle of microorganisms. It is only by the discovery and skills of the microbiologist that biologically pure cultures of microorganisms come into existence.

Alma Dietz said:

Microorganisms found in the soil are complex in kind and can not be taxonomically characterized without first producing a biologically pure culture. This clearly establishes that the "biologically pure culture" of Claim 5 is *not* found in nature; it is the product of a microbiologist.

Dr. Miller said:

The fermentation disclosed in application Serial No. 477,766 is conducted with a biologically pure culture of *S. vellosus*. A biologically *impure* culture of *S. vellosus* would *not* give the desired fermentation product under the conditions disclosed in application Serial No. 477,766, or possibly under *any* fermentation conditions.

* * * * *

It is clear to me that the "biologically pure culture" of Claim 5 is a product of a microbiologist and *not* a product of nature.

After considering these affidavits, the examiner adhered to his view, which he summarized in his Answer on the appeal to the board as follows:

Claim 5 is rejected under 35 USC 101 as drawn to nonstatutory subject matter. Claim 5 defines a microorganism, which is a product of nature * * *.

He thus ignored the opening words of claim 5, "A biologically pure culture of," which constitute a material claim limitation.

The board majority, in turn, ignored the examiner's ground of rejection. It did not even mention it until the end of its opinion where it said it did "not reach and [did not] need to decide" whether being a product of nature would preclude patenting, and said of the affidavits that they were "not germane to the issue which we consider is presented to us by the facts of this case." That issue, to which it devoted its opinion, it stated to be "whether or not a microorganism, being a living thing, is or is not within the realm of statutory patentable subject matter * * *." Like the *Chakrabarty* board, it said it had "not found any case directly in point." It then copied the *Chakrabarty* board's reasoning and came to the same conclusion.

This raises a technical procedural question which we dispose of at this point. Since *In re Wagenhorst*, 20 CCPA 991, 64 F.2d 780, 17 USPQ 330 (1933), it has been the rule that when the board affirms an examiner's rejection generally without reversing a ground the examiner relied on, that ground is assumed to be affirmed. See 37 CFR 1.196(a). We have an anomalous situation here in that the board affirmed on a *new* ground without so stating, not reaching the *sole* ground relied on by the examiner. Therefore, in case there is doubt as to whether the examiner's product-of-nature rejection is still an issue in this case, in the interest of judicial economy we rule on it now. It involves only a question of law and there is sufficient evidence in the record. See *Sylvestri v. Grant*, 496 F.2d 593, 181 USPQ 706 (CCPA 1974) (question of law of suppression under §102(g) need not be remanded for board's views); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973) (justice not served by remand in light of investment of time and effort made by parties). See also *In re Honeywell*, 497 F.2d 1344, 1350, 181 USPQ 821, 826 (CCPA 1974) (Rich, J., *concurring*) (remand not necessary where issue involves question of law which has been briefed). We hold that Bergy's claim 5 clearly does not define a product of nature.

There was a lengthy dissenting opinion by one member of the board, Acting Examiner-in-Chief Murray Katz, in which, after examination of numerous cases cited and others, he stated these conclusions:

* * * I do not believe that the fact that plants and bacteria have some properties in common is sufficient basis for holding that bacteria are to be excluded from patent coverage. * * *.

* * * I do not find it improper to claim living organisms * * *.

In view of the discussed cases, and since 35 U.S.C. 101 does not expressly exclude patents to living organisms, it is my opinion that living or-

ganisms, as claimed, may be patented if such claims also fulfill the other requirements of the statute.

Decision on the Merits

We adhere to our former decisions that Bergy's and Chakrabarty's appealed claims define subject matter that falls within the categories named in §101 and are thus "statutory subject matter."

This court *unanimously* believes it is not necessary that Congress shall have *foreseen* a new field of technology or useful art to bring it within §101. As the Supreme Court said in *Barr v. United States*, 324 U.S. 83, 90 (1945),

* * * if Congress has made a choice of language which fairly brings a given situation within a statute, it is unimportant that the particular application may not have been contemplated by the legislators. *Puerto Rico v. Shell Co.*, 302 U.S. 253, 257; *Browder v. United States*, 312 U.S. 335, 339, and cases cited.

Clearly, the language Congress chose to use in §101 fairly brings the appealed claims within the statute. To insist on specific Congressional foresight in construing §101 would be the very antithesis of the Constitutional and Congressional purpose of stimulating the creation of new technologies—by their nature unforeseeable—and their progressive development. This has been clear since *Kendall v. Winsor*, 62 U.S. 322, 328, (1859), wherein the Supreme Court said:

The true policy and ends of the patent laws enacted under this Government are disclosed in that article of the Constitution, the source of all these laws, viz: "to promote the progress of science and the useful arts," *contemplating and necessarily implying their extension, and increasing adaptation to the uses of society.* [Emphasis ours.]

The present recital of categories in §101, "*any* new and useful process, machine, manufacture, or composition of matter, or *any* new and useful improvement thereof" (our emphasis), has been the same ever since the Patent Act of 1793, except for substituting "process" for "art" and defining it (§100 (b)) to include art. For the nearly 200 years since, those words have been liberally construed to include the most diverse range imaginable of unforeseen developments in technology.¹⁰ The list is endless and beyond recitation. We merely suggest that the Founding Fathers and the Congresses of the past century could not have foreseen the technologies that have allowed man to walk on the moon, switch travel from the railroads to heavier-than-air craft, fill our houses with color TV, cure normally fatal diseases with antibiotics produced by cultures of molds (microorganisms), and give to schoolchildren at small cost pocket calculators with which they can produce square roots in microseconds through complex electronic circuitry on an "IC" (integrated circuit) so small the circuits are not visible to the naked eye.

American industry is on the threshold of a new advance in microorganism technology in which man is exploring more intensely and learning to better convert to his use the micro-world of living cells, the field of molecular biology, a new branch of a useful art which has existed for many years. According to the amicus brief filed on behalf of Genentech, Inc., its research has

¹⁰ See Wegner, *The Patentability of "New Manufactures"—The Living Invention*, "New Manufactures"—Encouragement of Pioneer Research," 1978 Patent Law Conference Coursebook (BNA) 253-62. (Mr. Wegner has extensively researched the question while a fellow at the Max Planck Institute for Foreign and International Patent, Copyright, and Competition Law, Munich, Germany. See Wegner, *Patent Protection for Novel Microorganisms Useful for the Preparation of Known Products*, 5 Int'l Rev. Indus. Prop. & Copyright L. 285 (1974); Wegner, *Patenting Nature's Secrets—Microorganisms*, 7 Int'l Rev. Indus. Prop. & Copyright L. 235 (1976).

resulted in the creation, for the first time, of a new bacterial organism capable of producing a human hormone. An article in *Business Week*, Dec. 12, 1977, page 128, entitled "A commercial debut for DNA technology," states that Genentech is a "tiny San Francisco company, just two years old," and that the hormone is "somatostatin [which] has potential both as a research tool and as a medicine, and variations on its structure might well open the way for a whole new family of drugs capable of treating diseases that today defy medicine's best efforts." The amicus brief states that, more recently, "Genentech and its City of Hope [Medical Center] collaborators applied the technology to create other microorganisms, and used them to produce no less than human insulin itself." This same work is referred to in the *Harvard Magazine* for September-October 1978, page 27, under the heading "Findings," where it is stated that Professor Gilbert and colleagues at Harvard "used gene-transplant techniques to get the common bacteria *Escherichia coli* to produce rat insulin." The statement adds, "The University has filed a patent application for parts of the successful procedure." The article refers to these procedures, using man-made microorganisms, as "bacterifactory (the production of needed substances by bacteria)."

We believe §101 and its predecessor statutes were broadly drawn in general terms to broadly encompass unforeseeable future developments, as broadly, we suggest, as section 2 of the Sherman Act, 15 USC 2. We have been shown no justification for the *Bergy* board's view that §101 "must be strictly construed."¹¹

¹¹P. J. Federico (a principal draftsman of the Patent Act of 1952 and author of "Commentary on the New Patent Act," 35 USCA 1) has explained the broad language of §101 as delineating a "general industrial boundary," in "Section 101: Subject Matter for Patents," *The Law of Chemical, Metallurgical, and Pharmaceutical Patents* 53, 58 (H. Forman, Ed. 1967):

As stated by Glascock and Stringham [Patent Law 22 (1943)]:

What we deal with here in each appeal is an industrial product used in an industrial process in a useful or technological art. See *In re Waldbaum*, supra. The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in Bergy's claim 5 and the modified microorganisms claimed by Chakrabarty are analogous in practical use to inanimate chemical compositions such as reactants, reagents, and catalysts used in chemical industry. According to an article cited but not relied on by the solicitor entitled "Microbiological Applications and Patents" by Harvey W. Edelblute in *The Encyclopedia of Patent Practice and Invention Management* at 567, edited by R. Calvert (1964), microbiological processes have long been used "to make beer, wine, cheese, bread, pickles and sauerkraut, rett flax, age tobacco, bate leather, produce silage and digest sewage." But more to the point here, in recent years, according to Edelblute, they have come to be used to "produce a vast variety of chemicals and drugs such as alcohols, ketones, fatty acids, amino acids, vitamins, antibiotics, steroids, and enzymes." Edelblute provides a "far from complete list" of chemical reactions carried out by microorganisms, which he names, which include oxidation, reduction, condensation, esterification, amination, deamination, phosphorylation, hydrolysis, decarboxylation, methylation,

"In the statute there is no basis for assuming that these [four terms—machine, manufacture, composition of matter, and process or art] represent four separate compartments of invention. Rather does the use of the four terms represent an effort to indicate the general industrial boundary of the single field of patentable invention." [Emphasis ours.]

The first three terms, machines, manufactures and compositions of matter, refer to physical things, while the fourth, process, refers to acts. Hence the general field may be considered as consisting of new things and new acts * * *.

dismutation, acrylation, and dehydration.¹² In short, microorganisms have long been important tools in the chemical industry, especially its pharmaceutical branch, and when such a useful, industrial tool is invented which is new and unobvious, so that it complies with those conditions for patentability, we see no reason to deprive it or its creator or owner of the protection and advantages of the patent system by arbitrarily excluding it at the outset from the §101 categories of patentable invention on the sole ground that it is alive. It is because it is alive that it is useful. The law has long and unhesitatingly granted patent protection to new, useful, and unobvious chemical compounds and compositions, in which category are to be found such important *products* of microbiological process as vitamin B-12 and adrenalin¹³ and countless other pharmaceuticals. We see no sound reason to refuse patent protection to the microorganisms themselves, or to pure microorganism cultures,—the tools used by chemical manufacturers in the same way as they use chemical elements, compounds, and compositions—when they are new and unobvious. In fact, we see no *legally* significant difference between active chemicals which are classified as “dead” and organisms used for their *chemical* reactions which take place because they are “alive.” Life is largely chemistry. We think the purposes underlying the patent system require us to include microorganisms and cultures within the terms “manufacture” and “composition of matter” in §101. Whether they *otherwise* qualify for patents under §102 and §103 is a question not before us. In short, we think the fact that microorganisms are

¹²Bacteria are universal biochemists * * *.” A. Bryan, C. A. Bryan, & C. G. Bryan, *Bacteriology* v (6th ed. 1962).

¹³*Merck & Co. v. Chase Chemical Co.*, 273 F. Supp. 68, 155 USPQ 139 (D. N.J. 1967); *Merck & Co. v. Olin Mathieson Chemical Corp.* 253 F. 2d 156, 116 USPQ 484 (CA 4 1958); *Parke Davis & Co. v. H. K. Mulford Co.*, 189 Fed. 95 (S.D. N.Y. 1911), *aff'd*, 196 Fed. 496 (CA 2 1912).

alive is a distinction without legal significance and that they should be treated under §101 no differently from chemical compounds.

There are two cases which have been persistently relied on by the examiners, the *Bergy* board, and the solicitor which we thought we had disposed of in our earlier opinions, but they turned up again in the *Bergy* petition for certiorari (p. 6), which is the only reason we consider it worthwhile to discuss them. The petition cited them only for what is admittedly “dicta” which is said to “suggest” that “living things” are not patentable. The cases are *Guaranty Trust Co. of New York v. Union Solvents Corp.*, 54 F.2d 400, 12 USPQ 47 (D. Del. 1931), *aff'd*, 61 F.2d 1041, 15 USPQ 237 (CA 3 1932); and *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974). Before discussing them, we point out that the *Bergy* petition misstated the issue. It is not whether *living things* are patentable. The “Question Presented” in the petition was stated to be “Whether a living organism is patentable subject matter under 35 U.S.C. 101.” That statement—typical of the PTO position from the outset—is overly broad, which is calculated to magnify its importance. We are not dealing with all living things, including man, fruits, vegetables, and flowers—all “organisms.” A correct statement of the *Bergy* issue would be: Is a man-made, biologically-pure culture of a microorganism, for industrial use in manufacturing an antibiotic, whose properties were discovered by the applicant for patent, excluded from the terms “manufacture” and “composition of matter” in 35 USC 101 because the microorganism is alive? To give a homely simple analogy, it is like asking whether a yeastcake or dried yeast powder is a “manufacture” or “composition of matter.” Yeast is alive.

All that this court’s *Mancy* case has been cited for is a bit of dictum bearing on a hypothetical situation which was not before us. The case involved claims to a *process* of producing a particular known antibiotic by aerobically cultivating a particular strain of *Streptomyces*

bifurcus. The claims were rejected for obviousness under 35 USC 103 on references showing various strains of other *Streptomyces* species used for the same purpose. We reversed, holding that *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973), was controlling and that the new *Streptomyces bifurcus* strain discovered by Mancy himself as part of the invention being claimed could not be used as prior art in determining the obviousness under §103 of his claims to a process of using it to produce the old antibiotic. In comparing the facts of the case before us in *Mancy* with the facts of *Kuehl*, we said (499 F.2d at 1294, 182 USPQ at 306):

We recognize the differences between this case and the situation in *Kuehl*, where the novel zeolite used as a catalyst in the claimed hydrocarbon cracking processes was itself the subject of allowed claims in the application. Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a "product of nature." However, it is not required for unobviousness of the method-of-use claims that the new starting material be patentable * * *.

If it is not clear from the context that we were not discussing what is or is not statutory subject matter within "§101 but only a difference between two cases which we found not to be a reason for distinguishing them, and that we were not expressing any view, even by way of dictum, on the patentability of living organisms as such, we now make it explicit that the thought underlying our presumption that Mancy could not have obtained a claim to the strain of microorganism he had described was simply that it *lacked novelty*. We were thinking of something preexisting and merely plucked from the earth and claimed as such,

a far cry from a biologically pure culture produced by great labor in a laboratory and so claimed. The dissenting board member was entirely correct in so interpreting our *Mancy* dictum. The examiner relied on it only to support his product-of-nature reasoning, and the board majority did not mention it, having abandoned that reasoning. Furthermore, it now appears to us, in light of what we have learned in this case about the separation and identification of new strains of *Streptomyces*, that our dictum was ill-considered. Had we known what we now know, we would likely have abjured the stated presumption.

Guaranty Trust Co. v. Union Solvents Corp., supra, was cited by the examiner as "especially pertinent" and again by the solicitor as a "judicial precedent" solely for the following passage appearing at the very end of the long trial court opinion (54 F.2d at 410, 12 USPQ at 57, emphasis ours):

Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the *life process* of a living organism. *Were the patent for bacteria per se, a different situation would be presented.* As before stated, the patent is *not for bacteria per se*. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set forth in the specification and claims. *Undoubtedly there is patentable subject-matter in the invention.* *Cochrane v. Deener*, 94 U.S. 780, 24 L.Ed. 139; *Risdon Iron & Locomotive Works v. Medart*, 158 U.S. 68, 15 S.Ct. 745, 39 L. Ed. 899; *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453 (C.C.A. 2); *Dick v. Lederle Antitoxin Laboratories (D.C.)* 43 F. (2d) 628. [6 USPQ 40 (S.D. N.Y. 1930)].

The statement the examiner relied on, "Were the patent for bacteria *per se*, a different situation would be presented," is a trite observation of minimal magnitude as precedent, dealing with a non-issue on which no

opinion was expressed. What we find of interest and, indeed, "pertinent" is the fact that the defendant urged the unpatentability of claims because they involved a life process of a *living* organism and *the court rejected the argument*. At the outset, the opinion states that one of the defenses was "non-patentable subject matter." The real plaintiff in the case was Commercial Solvents Corporation, exclusive licensee under the Weizmann patent in suit, which corporation was making butyl alcohol and acetone by the Weizmann bacteriological fermentation process, and, with its predecessors, had been doing so since 1918. In 1929 the production was 107,500,000 pounds. The trial court noted that "The record shows that an important and extensive new industry has now been developed and established upon the Weizmann process." It was very clear to the court that it was dealing with a life process for, in describing the invention, it said, "'Fermentation' is the chemical change, or the decomposition into new chemical compounds, of a substratum, by living organisms, such, for example, as yeast or bacteria." On the issue whether a process dependent upon living organisms and their life processes was patentable subject matter, the court had no doubts. In the last case cited in the above quotation, *Dick v. Lederle*, two years earlier the court had found a scarlet fever toxin and antitoxin and process of making the same to be patentable subject matter notwithstanding the employment of life processes in their preparation. On appeal in the *Guaranty Trust* case, the Third Circuit Court of Appeals affirmed per curiam on the opinion of the trial judge, commenting, inter alia, that it had been persuaded "that the invention disclosed in the patent created a new and important commercial enterprise * * *." 61 F.2d at 1041.

These decisions illustrate what we believe to have been the state of the law ever since, namely, that *processes*, one of the categories of subject matter specified in §101, are uniformly and consistently considered to be statutory subject matter notwithstanding the em-

ployment therein of living organisms and their life processes. Witness the action of the PTO in the present case in allowing the process claims. Other examples of such patentable process claims involving living bacteria are to be seen in the bacterial sewage treatment cases of which one is *City of Milwaukee v. Activated Sludge, Inc.*, 69 F. 2d 577, 21 USPQ 69 (CA 7 1934). (See quoted claims 8 and 10 of reissue patent No. 15,140 in fn. 4.) A still earlier one is the *Cameron Septic Tank Co.* case cited in *Guaranty Trust* and decided by the Second Circuit Court of Appeals in 1908, wherein the trial court was reversed and bacterial-action process claims were held valid and infringed. (The original "septic tank.") It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not affect their status under §101.

Inapplicability of Plant Protection Legislation

In our former *Bergy* opinion, we disposed of the plant patent legislation argument by saying:

Nor are we influenced by the legislative history of the Plant Patent Act of 1930 in the course of which nobody had anything to say about patent protection for microorganisms * * *. The collective mind of Congress was not turned in that direction.

Since the PTO solicitor made it clear on the reargument that the plant patent legislation is the *sole* basis on which the PTO contends for exclusion of the appealed inventions from §101, and since our position was commented on in two dissenting opinions,¹⁴ we now set

¹⁴One of which opinions, after reargument, has now been abandoned and changed to a concurrence.

forth in extenso the historical support for our earlier summary statement.

The PTO position places particular emphasis on the Plant Patent Act of 1930 (ch. 312, 46 Stat. 376, now codified as 35 USC 161 et seq.), legislation directed specifically to plant breeders and conspicuous for its total inattention to anything other than the plant varieties of the type that Luther Burbank had then recently popularized. Nonetheless, both boards used that act to justify affirming the rejections of the claims in issue here, preliminarily overgeneralizing the question in terms of whether a "living thing" is patentable subject matter, and then proceeding along the logic of this syllogism:

[R.S. §4886 did] * * * not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturists and agriculturists * * *.

* * * We believe that the legislative history [of the Plant Patent Act] reveals a clear Congressional intent that *plants* were not covered by the predecessor of 35 U.S.C. 101.

[Both plants and microorganisms are living organisms.]

[Therefore,] * * * we do not believe that the terms "manufacture" or "composition of matter," as employed in 35 U.S.C. 101, were intended to encompass *any* living organisms, whether plants or the microorganism appellants are claiming here. [Emphasis ours.]

In analyzing the issue in this way, the PTO has made several errors. First, it ignored fundamental tenets of statutory construction accepted by the commentators and the Supreme Court; second, it failed to consider the explicit purpose of the Plant Patent Act; and, third, it misused portions of the legislative history of that act to substantiate propositions concerning living organisms generally, on which Congress itself had not spoken.

1. Statutory Construction

The principal mistake of the PTO was to look to the legislative history of the Plant Patent Act for evidence of the intent of a *previous* Congress, saying, in effect, that if Congress in 1930 passed an act extending patent protection to plant breeders, then Congress in 1874 must not have intended that "manufactures" and "compositions of matter" in R.S. §4886 include *any* living organism. The violence done by this analysis resides in ascribing to a preceding Congress an intent that the members of that Congress did not themselves state. It is for this reason that the Supreme Court has consistently and unequivocally concluded that:

"[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one."

United States v. Price, 361 U.S. 304, 313 (1960); *accord*, *United States v. Southwestern Cable Co.*, 392 U.S. 157, 170 (1968); *United States v. Philadelphia National Bank*, 374 U.S. 321, 348-49 (1963); *Rainwater v. United States*, 356 U.S. 590 (1958); *United States v. United Mine Workers*, 330 U.S. 258, 281-82 (1947). In response to an argument remarkably similar to that made here by the PTO, the Supreme Court, in *Rainwater v. United States*, *supra*, 356 U.S. at 593, rejected an invitation to interpret the meaning of an act of Congress by reliance on a later amending act with the following comment:

At most, the * * * amendment is merely an expression of how * * * [a later] Congress interpreted a statute passed by another Congress more than half a century before. Under these circumstances such interpretation has very little, if any, significance.

Significantly, the Court there noted the topic of primary concern to Congress, as evidenced by the express language and legislative history of the amendment, and

observed that congressional action regarding that topic "is of little value in deciding the applicability" to the original act of subject matter related to, but not within the scope of, the amendment. *Id.* In the present cases we are similarly concerned with subject matter, microorganisms, only arguably related to, but clearly not within the scope of, the 1930 Plant Patent Act. We must recognize that the Plant Patent Act is, in this instance, "of little value in deciding the applicability" to microorganisms of 35 USC 101, the successor statute to R.S. §4886.

The improper use of legislative history by the PTO illustrates a reason for the concern of Justices Jackson and Frankfurter in *United States v. Public Utilities Commission of California*, 345 U.S. 295 (1953), where they expressed the following apprehension:

[Courts should reach their decisions] by analysis of the statute instead of by psychoanalysis of Congress. When we decide from legislative history * * * what Congress probably had in mind, we must put ourselves in the place of a majority of Congressmen and act according to the impression we think this history should have made on them. * * * That process seems to me *not interpretation* of a statute *but creation* of a statute. [Emphasis ours.] [345 U.S. at 319 (Jackson, J., concurring).]

Justice Frankfurter added:

It is one thing to construe a section of a comprehensive statute in the context of its general scheme, as that scheme is indicated by its terms and by the gloss of those authorized to speak for Congress, either through reports or statements on the floor. It is a very different thing to extrapolate meaning from *surmises and speculation and free-wheeling utterances*, especially to do so *in disregard of the terms in which Congress has chosen to express its purpose*. [Emphasis ours.] [345 U.S. at 321 (Frankfurter, J., concurring).]

In the cases before us, the PTO has chosen to interpret the Plant Patent Act "in disregard of the terms in which Congress has chosen to express its purpose" in passing the act. As we will show, Congress expressed its purpose in terms of a desire to extend the benefits of the patent system to the field of agriculture. The PTO has engaged in pure speculation in using the Plant Patent Act of 1930 as evidence of the intent of a preceding Congress despite the total absence in that act's legislative history of any support for such a position. Such speculation cannot tell us what Congress intended by the terms "manufacture" or "composition of matter" when they were reenacted in 1874 into R.S. §4886 (now in 35 USC 101).

One further point on statutory construction merits attention. The solicitor argues in the *Chakrabarty* brief that we must read the 1930 amendments to R.S. §4886 *in pari materia* with the statutory provision it amended. His point seems to be that the amendment is evidence that Congress did not intend to declare existing law, or clarify what was already includable in the expressions "manufacture" and "composition of matter" employed in R.S. §4886, but rather intended to add to those categories a new class of statutory subject matter not within the compass of R.S. §4886. As the PTO has done throughout this case, the solicitor over-generalizes Congress' intent to bring certain *plants* within the patent laws to the point where it is asserted that Congress intended for the first time to include *living things* within R.S. §4886. He then proceeds to argue that specific terms in a statute prevail over general terms, citing *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222 (1957), and concludes that the specific terms of R.S. §4886 relating to plants must be construed as the sole and exclusive provisions controlling what kinds of living organisms are patentable subject matter.

We think the solicitor paints with too broad a brush. In our view, the specific terms of the 1930 amendment

deal solely with asexually reproduced *plants*, and application of the principle stated in *Fourco Glass* leads only to the conclusion that only the types of *plants* there enumerated are statutory subject matter. As we shall show, the terms and legislative history of the 1930 amendment deal exclusively with agriculture, and aside from the few scattered casual remarks made concerning the subject of animate vs. inanimate things seized upon by the PTO as a toehold for its argument to the contrary, Congress was not at all concerned with the presence or absence of "life" in the plants with which it was concerned.¹⁵

Additionally, we note that the approach to statutory construction employed in *Fourco Glass* represents an

¹⁵ Under the well-established principle of statutory construction, the words of a statute are to be given their common, ordinary meaning. *Columbia Water Power Co. v. Columbia Electric Street Railway Light and Power Co.*, 172 U.S. 475, 491 (1899); accord, *Woolford Realty Co. v. Rose*, 286 U.S. 319, 323 (1932); *Old Colony Railroad Co. v. Commissioner*, 284 U.S. 552, 560 (1932). While the term "plant" taxonomically includes many living organisms, most of these things are not included in the common, ordinary meaning of the term, which is limited to those things having roots, stems, leaves and flowers or fruits. Our thorough examination of the express terms of the 1930 act, as well as its legislative history, confirms our belief that Congress was using the term in the common, ordinary sense just defined, and was not at all concerned with living organisms generally. This court has already decided this very point. See *In re Arzberger*, 27 CCPA 1315, 112 F.2d 834, 46 USPQ 32 (1940). The strained, result-oriented analysis made by the PTO is merely an attempt to bootstrap its "living things" argument in order to place it within the purview of the 1930 act. Similarly, the partial definition of "plant" selected by the dissent at note 2 from the much longer definition in *Webster's Third New International Dictionary* 1731 (unab. 1971) encompasses far more than the common, ordinary meaning of the word with which the 1930 Congress dealt. The evident intent of Congress should not be obscured by deliberately over-refining the meaning of words where Congress has given no indication that it intended such meaning.

exception to the rule of construction that provisions of a statute should be harmonized if possible. The Supreme Court has stated that its task "is to give the act 'the most harmonious, comprehensive meaning possible' in light of the legislative policy and purpose." *Weinberger v. Hynson, Wescott & Dunning Co.*, 412 U.S. 609, 631-32 (1973); accord, *Federal Power Commission v. Panhandle Eastern Pipeline Co.*, 337 U.S. 498, 514 (1949). See also C. Sands, 2A *Statutes and Statutory Construction* §51.05 at 315 (4th ed. 1973); 82 C.J.S. *Statutes* §347 at 720 et seq. (1953). Elsewhere in this opinion we have indicated the established administrative practice of the PTO in allowing claims directed to living matter and life processes, which practice is entitled to weight as evidence of the meaning of a statute. *United States v. American Trucking Associations, Inc.*, 310 U.S. 534, 549 (1940). We think the plant provisions may be harmonized with the remainder of R.S. §4886 by recognizing that the 1930 amendment dealt solely with asexually reproduced plants and that the remainder of that section had already been construed by the PTO to include living things other than plants. Thus we find the test in *Fourco Glass*, which says nothing to the contrary, to be inapplicable here.

To conclude, no doubt it is proper to look to the legislative history of the Plant Patent Act in construing *that act*; but looking at it to find the purpose and intent of a previous Congress, on the basis of the PTO's unfounded overstatement of what the purpose of the amending Congress was, is not even rational speculation. We turn, now, to the Plant Patent Act itself.

2. The Purpose of the Plant Protection Legislation

What Congress was trying to accomplish by the Plant Patent Act is clear. The PTO seems to have gone astray by generalizing the plants with which Congress was concerned into the broad category of "living organisms," with which Congress was totally uncon-

cerned, and then proceeding to find in the legislative history nonexistent inferences about living organisms as a class, inclusive of everything not dead. The proper approach is to "give the statute effect in accordance with the purpose so clearly manifested by Congress." *Commissioner v. Bilder*, 369 U.S. 499, 504 n. 5 (1962).

The statute and its purpose are most accurately viewed from the point of historical perspective.¹⁶ At the inception of the American patent system in 1790, the growth of the new country demanded a stimulus for the manufacture of all kinds of goods for the benefit of the public. This field of manufacturing was generally regarded as "industry"; its domain was the production of any and all things made by the hand of man. At the time, existing industry was not sufficient to supply even agriculture with its needs, which found itself with limitless land, a shortage of manpower, and a crying need for tools and machines.

In the mid-1800's, however, it became apparent that scientific principles could be applied to agriculture and horticulture, and, indeed, would necessarily someday have to be. Thus, in 1862 the Morrill Land Grant Act¹⁷ established agricultural colleges in every state of the union, and agriculture and horticulture experiment stations to promote research were established under the Department of Agriculture, an offspring of the Patent Office and its first Commissioner, Ellsworth, who collected seeds at the Patent Office and distributed them throughout the country. 1840 Pat. Off. Report 2.

When the slow growth of American horticulture and agriculture was exacerbated by the general depression that struck the farming community in the early 1900's, action on Capitol Hill became intense as the farm lobby cried for relief. As a result, bills were proposed in Con-

¹⁶"[S]tatutes are construed by the courts with reference to the circumstances existing at the time of the passage." *United States v. Wise*, 370 U.S. 405, 411 (1962).

¹⁷Ch. 130, 12 Stat. 503 (1862).

gress for support of horticulture and agriculture¹⁸ through patent protection similar to that of the 1930 Plant Patent Act.¹⁹

Eventually, after Luther Burbank had dramatized the economic plight of the amateur horticulturists, the clamour in Congress for legislative help to plant breeders culminated in the Plant Patent Act of 1930. The statute was, in toto, an effort to apply the patent system where it had not been applied before in order to fuel the fire under plant breeding and to protect the experimenters in that as yet nonindustrial field. There were legal niceties to overcome—the product-of-nature rejection had already been applied by the Patent Office to pre-Burbank plants—but the purpose of Congress in passing the act is beyond doubt.

In this light, we turn to the express purpose of the Plant Patent Act, as set forth in the contemporaneous House and Senate Reports:²⁰

¹⁸H.R. 5435, 52nd Cong., 1st Sess (1892), A bill for the advancement of the science of agriculture.

H.R. 18851, 59th Cong., 1st Sess. (1906), A bill to amend the laws of the United States relating to patents in the interest of the originators of horticultural products.

S. 59, 60th Cong., 1st Sess. (1907), A bill to amend the laws of the United States relating to patents in the interest of the originators of horticultural products.

H.R. 21951, 60th Cong., 1st Sess. (1908), A bill to amend the laws of the United States relating to patents in the interest of the originators of horticultural products.

H.R. 24010, 61st Cong., 2d Sess. (1910), A bill to amend the laws of the United States relating to patents in the interest of originators of horticultural products.

¹⁹Statements at the hearings on H.R. 18851, *id.*, indicate that identical purposes and problems were considered in 1906.

²⁰S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930) and H. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930).

I. Purposes of the Bill

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry. The bill will remove the existing discrimination between plant developers and industrial inventors.

After this statement of purpose, both reports then commence discussions of "Stimulation of Plant Breeding," noting its embryonic state:

Today plant breeding and research is dependent, in large part, upon Government funds to Government experiment stations, or the limited endeavors of the amateur breeder.

Id. at 2. Thus, Congress had in mind the stimulation of a *field of endeavor* that, unlike chemistry, for example, had not as yet flowered into an industry. Hence, to "assist in placing agriculture on a basis of economic equality with industry," it extended the benefits of the patent system to these as yet nonindustrial plant breeders like Luther Burbank. What is crystal clear is the intent of Congress to extend the patent system to a *nonindustrial area*, ignoring completely the fact that plants were alive.

The committee reports and Congressional debates and hearings are replete with expressions indicating the perceived distinction between existing patent laws and the proposed Plant Patent bill to be in the *fields of endeavor* to which they were directed, the former to industrial pursuits, the latter to an art still in the research and experimental stage.²¹ The unavoidable con-

²¹ See, e.g., the statement of sponsoring Congressman Purnell, Hearings on H.R. 11372 before the Committee on Patents, 71st Cong., 2d Sess. 2-3 (1930). We note that statements of the

clusion is that the purpose of Congress was precisely what Congress said it was—to offer to the useful art of *plant breeding* in the fields of horticulture and agriculture the benefits of the patent system that had theretofore been available only to industry.

The secondary purpose of the Plant Patent Act was to avoid the judicial interpretation which had been placed on then-existing patent laws that *products of nature* are not statutory subject matter. Until the time that Burbank made famous the art of plant breeding, plants were regarded as products of nature, unaffected by the hand of man, and thus not subject to patent protection.²²

The state of the patent law with reference to plants is shown in *Ex Parte Latimer*, 1889 C.D. 123, 46 O.G. 1638 (Comr. 1889). Latimer claimed the fiber of the needle of the *Pinus australis* tree, the rejection of which claim the Commissioner of Patents affirmed as directed to a product of nature, as follows (p. 125):

It cannot be said that the applicant in this case has made any discovery, or is entitled to patent the idea, or fact, rather, that fiber can be found in the needle of the *Pinus australis*, or that it is a longer fiber than can be found in other leaves, or that it possesses more or less strength of fineness, because the mere ascertaining of the character or quality of trees that grow in the forest and the construction of the woody fiber and tissue of which they are composed is not a patentable invention, recognized by the statute, any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found * * *. The result would be that

legislation's sponsor deserve substantial weight in interpreting the statute. *Federal Energy Administration v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976).

²² Wegner, *The Patentability of "New Manufactures"—The Living Invention*, "The Product of Nature of Early Days," *supra* note 10, at 274-80.

* * * patents might be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible.

* * * * *

[The product here claimed] is a natural product and can no more be the subject of a patent in its natural state when freed from its surroundings than wheat which has been cut by a reaper or by some new method of reaping can be patented as wheat cut by such a process.

Until the time plant breeding began its growth, this was the controlling law in the Patent Office, and was apparently understood as such in both the legal and horticultural communities. In 1923, the commentator Thorne noted efforts to afford protection to plant propagators, but, after citing *Latimer* as "set[ting] forth the general stand taken in these matters" in the Patent Office, stated that "plants * * * grow as natural products, and as such they are not discoveries which are subject to patentable [sic] protection." H. Thorne, *Relation of Patent Law to Natural Products*, 6 JPOS 23, 25 (1923). E. Stringham, in one of his many patent law texts, *Outline of Patent Law*, at 144 (1937), indicates at §1226 under "product of nature" that a "growing plant, as such, or any part of it, is patentable, only to the extent of the new statute [the Plant Patent Act]," showing his appreciation that plants not propagated by man are natural products. In the horticultural field, Cook, Editor of the *Journal of Heredity* (which probably gave more attention to the plant patent idea than any other publication)²³ and author of a myriad of articles on the subject, commented:

It is a little hard for plant men to understand why [Article 1, §8] of the Constitution should not have been earlier construed to include the promotion of

²³ R. Aliyn, *The First Plant Patents*, at 58 (1934).

the art of plant breeding. The reason for this is probably to be found in the principle that natural products are not patentable.^[24]

That the 71st Congress was aware of the past objection that plants were products of nature is evidenced by both the Senate and House Reports which dealt with this point extensively in "Legal Phases of the Bill." It concluded that the product-of-nature rejection would be inapplicable to asexually produced plants, stating:

* * * a plant discovery *resulting from cultivation is unique*, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man * * *

It is obvious that nature originally creates plants but it can not be denied *that man often controls and directs the natural processes* and produces a desired result. * * *

Furthermore, there is no apparent difference, for instance, between the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter * * *. [S. Rep. No. 315, supra, at 6-7.]

Following an objection raised during the House hearings by Secretary of Commerce Lamont that he seriously doubted that patents on plants *not bred by man* (i.e., found in nature and then cultivated by man) would be constitutional, "newly found" plants were deleted from the proposed statute. With that, the product-of-nature objection was avoided, and the way cleared for passage of the bill.

In support of the PTO position that in 1930 Congress was concerned with all living organisms, the solicitor points to the following quotation from Secretary of Ag-

²⁴ Florists Exchange and Horticultural Trade World (July 15, 1933), at 9.

riculture Hyde, appearing in a letter included in the Senate and House Reports, S. Rep. at 9-10, H. Rep. at 10-11:

[The purpose of this bill] is sought to be accomplished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inanimate nature.

We give no weight to Secretary Hyde's "understanding" of the law. There is no reason to attribute it to Congress. As the reports show, he wrote the letter because he was asked for his views on the proposed participation of his department in the *administration* of the new law since the bill proposed that his department cooperate with the Patent Office. To rely on his understanding is grasping at a straw.

Finally, we note another important reason for amending the statutes to permit patenting of plants. Under existing law, it was not seen how a plant could be described in a written document so as to comply with the written description requirement pertaining to "utility" patents. To solve this problem, section 4888 of the Revised Statutes, then in force, was amended by adding to the end, "No plant patent shall be declared invalid on the ground of noncompliance with this section if the description is made as complete as is reasonably possible." The substance of this sentence is today the first sentence of 35 USC 162.

In this connection, we note further that while that provision was needed to secure protection to the plant breeders, no such modification of the statutes has ever been necessary to make possible the patenting of industrially useful microorganism inventions such as those of Bergy and Chakrabarty, which are readily so described and claimed as to comply with the written description and claiming provisions of 35 USC 112.

We briefly mention the plant Variety Protection Act of 1970 (7 USC 2321 et seq.). which provides for "certificates of plant variety protection" to be issued by the Department of Agriculture to developers of "Soybeans * * * [and other] major U.S. crops, like cotton, wheat, barley, oats, and rice, for example * * * ." That act was no more than an extension of protection to developers of plants that had been specifically excluded from the Plant Patent Act of 1930.

The 1930 act applies only to plants propagated by asexual reproduction. As was stated by Congressman Mayne in the House hearings on the 1970 act:

Those plants which reproduce asexually such as by budding and grafting have been covered by the patent law since 1930. There is no justification for not extending the same coverage to sexually reproduced plants. [Hearings H.R. 1290, 91st Cong., 2d Sess., 116 Cong. Rec. 40296 (1970).]

This clearly indicates that Congress was again concerned solely with plants. The 1970 act is cited by the PTO for the exclusion in 7 USC 2402(a) of "fungi, bacteria, or first generation hybrids * * * ." The question is, why? We agree with Chakrabarty's rational explanation that the exclusion from protected varieties in §2402(a) was merely the legislative recognition of this court's ruling in *In re Arzberger*, 27 CCPA 1315, 112 F.2d 834 46 USPQ 32 (1940), which interpreted the Plant Patent Act of 1930 to include only plants in the layman's sense and not the bacterium for which Arzberger unsuccessfully sought protection *as a plant* under *that act*. Our reading of the Plant Variety Protection Act of 1970 provides no support for the PTO's reasoning. The solicitor's use of it suffers from the same flaw as does his use of the Plant Patent Act; it cannot be used to attribute to a preceding Congress, the 82d Congress that passed the 1952 patent act, an intent not expressed by that Congress. There is not a word in either Title 35, United States Code, or in its legislative

history, which supports the assertion that the 82nd Congress had in mind a general distinction between living and non-living subject matter. The 1970 act was no more concerned with living things in general than was the 1930 amendment to R.S. §4886.

*This Decision Does Not
"Extend" the Patent Laws*

"The sky is falling, the sky is falling!" cried Chicken Little. The CCPA is indulging in "wholesale judicial legislation," says the solicitor, by "extending" the patent laws to "encompass living organisms—life itself." Come, let us return to reason. The solicitor himself tells us the precise question we have here is one of first impression *in the courts*. While that is probably so, the fact that it has not come to a court before in this precise form does not mean that it has never before been considered where it matters—in the PTO. We shall presently show how the PTO has regularly been issuing patents on non-process inventions involving "life itself," even, potentially, in the cases before us now, apart from the appealed claims. Being a case of first impression in the courts means that there is no prior precedent to be extended or overruled, as there was in *Deepsouth*, previously discussed.

With similar hyperbole, the *Bergy* petition for certiorari says that since "the number of living things is vast," our prior decision in that case "opens an enormous range of subject matter to patentability," and threatens that, unless reversed, "the policy problems of genetic engineering, already controversial, will be further complicated by crystallized patent considerations," whatever that may mean. From our modest exposure to the realities of the patent system we judge the range of subject matter open to patentability to be enormous in any case. It is heartening to think how many useful things may yet be invented and we are not moved to be restrictive in our interpretation of §101 by mere num-

bers. An appropriate rejoinder we think is, "The more the better." Chemical compounds, to take an example, presumed "dead" though very active in various environments, have unquestionably always been regarded as both "manufactures" and "compositions of matter," yet we have never heard that their possible number is other than infinite. When we examine "living" cells, it appears that they too are chemical compounds assembled in infinite complexity with an added facility for replication. From the standpoint of construing the patent statutes, we do not see, and the PTO has not shown us, *any sound reason* for making the distinction it seeks to make here between the living and the dead. Its arguments are mere lawyers' techniques to support an a priori conclusion.

With respect to past PTO construction of the word "manufacture" in the statute, Genentech's amicus brief informs us that Louis Pasteur in 1873 obtained United States patent 141,072 containing this claim:

2. Yeast, free from organic germs of disease, as an article of manufacture.

Yeast is alive, else we would not have beer and bread would not rise. The law's statement of categories of inventions which *may* be patentable was the same in 1873 as it is today.

The Patent, Trademark, and Copyright Research Institute of the George Washington University, formerly affiliated with its law school, published a quarterly called *IDEA*. In 10 *IDEA* 87 (1966), a student paper was published entitled *Microbiological Plant Patents*, by Daus, Bond, and Rose. The authors were all Assistant Examiners in the United States Patent office. The paper was a critical examination of this court's decision in *In re Arzberger*, 112 F.2d 834, 46 USPQ 32 (CCPA 1940). At page 94 they stated, "The existence of patents drawn to living organisms and cultures used in foods, insecticides, et cetera, is indicated in the footnote

below." We reproduce the footnote in pertinent part (emphasis ours):

³⁶ The following are *typical* of living matter patented as compositions of matter and are *by no means exhaustive*: (The number of the patent, its month of issue, the patentee and the Patent Office classification are given in that order).

1) Bacteria

3,133,066 12-1963 Emond 167-13

Claims 1 and 2 are drawn to composition containing oil and *Bacillus thuringiensis* spores. Reference to the patent file indicates emphasis on the living character of the composition, and of synergistic effects.

2) Yeasts

2,919,194 12-1959 Johnston 99-96

Claim 21 is drawn to dry baker's viable yeasts comprising the yeast, less than 8% moisture.

3) Yeast and Bacteria

1,894,135 1-1933 Torok *et al.* 99-96

Claim 10 is drawn to "a yeast preparation containing lactic acid separated from their nutrient medium."

4) Mushroom mycellia ("spawn")

2,262,851 11-1941 Lescarboursa 47-111

Claims 1-10 are drawn to pulps overgrown with mushroom mycellium.

5) Virus

2,271,819 2-1942 Green 167-78

Claims 3 and 4 are drawn to a distemper virus vaccine described by the process for its production.

2,518,978 8-1950 Cox *et al.* 167-80

Claim 5 is drawn to a hog cholera virus developed by a specified process.

2,966,433 12-1960 Cox 167-78

Claims 1 and 2 are drawn to live polio viruses made by a specified process.

6) Plant seeds

3,080,285 3-1963 Openwald, *et al.* 167-65

Claims 1-4 are drawn to seed covered with medication.

7) Eggs

3,088,865 5-1963 Wernicoff *et al.* 167-531

Claim 8 is drawn to an egg treated by the method of addition of hormones.

8) Eggs plus bacteriophages

2,851,006 9-1958 Taylor *et al.* 119-1

Claims 1-8 are drawn to eggs inoculated with *Salmonella* phages (a virus which attacks *Salmonella* bacteria), providing resistance thereto.

It is not possible to reconcile the assertion that we are "expanding" patent law to cover living things with the PTO's issuance of the foregoing patents. Neither is it possible to reconcile the contention with the performance of the PTO in the very cases before us.

We quoted Chakrabarty's *allowed* claim 30 above (p. 45). In simplified terms, the invention it defines is a "carrier" which will float on water and the bacterium Chakrabarty invented, as defined in rejected claim 7 (p. 44), "carried thereby." To simplify matters further, we pointed out that the preferred carrier described in the specification is straw. *Allowed* claim 31 reads "The inoculated medium of claim 30 wherein the carrier medium is straw." Thus, the PTO is willing to issue a patent with claims to Chakrabarty's new bacterium carried on straw. The bacterium is just as much *alive* when carried on straw as when it is by itself or carried in a bottle. Is not such a patent on a "living thing"? But is it a patent on "life itself"? Certainly not. Presumably the PTO considers the subject matter of all of the *allowed* claims to be within §101, or it could not have *allowed* them. The PTO does, therefore, treat §101 as inclusive of "living things," whether or not some members of the board think it should be otherwise. *Excluding* all of them from §101 is to change the law.

In Bergy's case, all of his *allowed* claims define processes in which a living organism is the active force which causes the process to proceed. As we said above, we do not see the logic of allowing claims to processes which depend for their operation on a living organism

while denying claims to the organism or a pure culture of it *merely* because it is alive.

One final point on "extension" arises because the *Bergy* petition for certiorari (p. 7) states:

As this court stressed in *Gottschalk v. Benson*, 409 U.S. 63, 72-73, policy decisions concerning the extension of the patent laws to *new fields* are for Congress, not the Courts. Accordingly, where *new technologies* are involved it is particularly important for the courts to interpret the patent laws so that "the prerequisites to obtaining a patent are strictly observed." [Emphasis ours.]

Apart from the fact that patentable inventions in general are related to new fields and new technologies, a sufficient answer is found in the solicitor's admissions at oral argument on remand that "the technology in a very broad sense is very old"; "The technology here is not new, it is old"; and "We're not talking about new technologies here." Moreover, *Benson* was discussing computer software or program patentability, a subject on which the President's Commission on the Patent System had made a recommendation, suggesting there should be no patents on "Programs," and the Court had observed "technological problems" in patenting such inventions. No such problems in examining inventions like those of the appealed claims have been suggested. The PTO has been handling them for years. They are easier to handle than many "chemical" cases.

We will comment briefly on the PTO suggestion that we are "legislating," deciding these cases on our own notions of public policy, *determination* of which should be left to Congress, and that we should not reverse these two board decisions without a positive "signal" from Congress that it is in accord with its desires. We think the facts speak for themselves. Admittedly, this is a case of first impression in the courts, which means, simply, that this court *has* to decide whether the biologically pure culture of *Bergy* and the newly

created bacterium of Chakrabarty do or do not fall within the term "manufacture" or the term "composition of matter" in §101. If the statute is not clear, if there is any room for "interstitial judicial legislation" by us, it is certainly still our duty to *make a decision*. But we find the statute clear on its face and have no difficulty in finding the claims to be within the statutory terms. The terms are broad: "any * * * manufacture, or composition of matter." If we had any doubt about the propriety of giving those words a broad interpretation, it would be dispelled by the identical statement in the House and Senate reports accompanying the 1952 reenactment, quoted *supra*, that "a machine, or a manufacture * * * may include *anything under the sun that is made by man*." (Emphasis ours.)²⁵ That certainly suffices to dispose of the *Bergy* board's "view that 35 U.S.C. 101 must be strictly construed." That leaves no interstices. As for "wholesale judicial legislation," the assertion falls by the weight of its own extremism.

Faced with the necessity of rendering a decision one way or the other on whether these inventions are encompassed by §101, there being no prior decisions to guide us, we merely carry out our normal judicial function in deciding to say yes rather than no. We look at the facts and see things that do not exist in nature and that are man-made, clearly fitting into the plain terms "manufacture" and "compositions of matter." We look at the statute and, plainly, it appears to include them. We look at its legislative history and are confirmed in that belief. We consider what the patent statutes are intended to accomplish and the Constitutional authori-

²⁵ We recognize that, at the time the statement was made, its authors realized that Congress did not intend the term "manufacture" in §101 to include plants, which were specifically provided for elsewhere. It is with this in mind that we take the quoted statement as an expression of congressional will that the term "manufacture" otherwise be given the broadest possible interpretation.

zation, and it appears to us that protecting these inventions, in the form claimed, by patents will promote progress in very useful arts. When we merely *determine* the policy underlying a statute we are not *making* policy. The policy was established by the Founding Fathers and by Congress long ago. Our "notions" of what it is are derived from the study of legal history wherein we find our "signals."

Rather, it seems to us, it is the PTO, not this court, that is attempting to legislate. It may have reasons for not wanting to examine the appealed claims for patentability under §§ 102 and 103, but if so, it has not revealed them. (It did have such reasons in the case of computer programs, and made the most of them.) For whatever reason, it decided to reject, first on one ground and then on another, and then set out, lawyer-like, to devise unduly exaggerated justifications spiced with bits and pieces from wholly unrelated plant-patent legislation from nearly half a century ago. We think the Supreme Court gave us our "signal" in *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933), where it said:

We should not read into the patent laws limitations and conditions which the legislature has not expressed.

DECISION

Appeal No. 76-712

The decision of the board affirming the rejection of claim 5 of Bergy et al. application serial No. 477,766 is *reversed*.

Appeal No. 77-535

The decision of the board affirming the rejection of claims 7-9, 13, 15, 17, 21, and 24-26 of Chakrabarty application serial No. 260, 563, is *reversed*.

REVERSED

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

Appeal No. 76-712
Serial No. 477,766

IN THE MATTER OF THE APPLICATION
OF

MALCOLM E. BERGY, JOHN H. COATS,
AND VEDPAL S. MALIK

Appeal No. 77-535.

Serial No. 260,563

IN THE MATTER OF THE APPLICATION
OF

ANANDA M. CHAKRABARTY

Before MARKEY, *Chief Judge*, RICH, BALDWIN, LANE
AND MILLER, *Associate Judges*.

BALDWIN, Judge, concurring

Although I agree with portions of the majority opinion, I do not subscribe to the view stated therein that the Supreme Court's opinion in *Parker v. Flook*, 437 U.S. 584, 198 USPQ 193 (1978), has no bearing on these appeals. It is only after reconsidering the subject matter of these appeals in the light of the precedents cited in the *Flook* opinion that I modify my former position

and now concur in the result reached by the majority.

The words of 35 USC 101, in defining areas of patentable subject matter, are quite clear on their face. This statute, while not as sweeping as its constitutional basis, is expansive in its scope. Indeed, the words of both the Senate and House Reports on the Act indicate that §101 is to "include anything under the sun that is made by man."¹ Complementary to this concept is the fact that the Patent Act was intended to be, generally, a codification of the law as it existed in 1952.² In the context of §101, the law was not drawn on a clean slate. Although this section pertains to *any* invention belonging to one of the listed classes of subject matter, decisions of the Supreme Court preclude a literal interpretation of the section.

These Supreme Court decisions have noted certain categories of subject matter that, although falling within the dictionary definitions of process, manufacture or composition of matter, nonetheless do *not* comprise statutory subject matter. The Court's opinion in *Parker v. Flook*, *supra*, explores the rationales behind these judicially-created exceptions and provides citations to other decisions of the court which are particularly germane to the appeals before us. These cases include *O'Reilly v. Morse*, 56 U.S. (15 How.) 61 (1853); *Le Roy v. Tatham*, 55 U.S. (14 How.) 155 (1852); *Tilgham v. Proctor*, 102 U.S. 707 (1880); *Eibel Process*

¹ See H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952); S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952).

² See generally, the Supreme Court's discussion in *Graham v. John Deere*, 383 U.S. 1, 3, 148 USPQ 459, 461 (1966). Additionally, Chairman Bryson's comments (discussing, *inter alia*, §101 and inventions involving principles of nature) in Patent Law Codification and Revision: Hearings on H.R. 3760 before Subcomm. No. 3 of the House Comm. on the Judiciary, 82d Cong., 1st Sess. 121 (1951), specifically noted that "[t]here is no intention to change the law as it is presently written; the purpose is just to make it clearer."

Co. v. Minnesota and Ontario Paper Co., 261 U.S. 45 (1923); *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86 (1939); and, *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

Although many of these decisions are far removed in time, and involve crude technologies when compared to those of Bergy and Chakrabarty, the opinions supporting these decisions voice a concern of the Supreme Court that a patentee not obtain an effective monopoly over that which is called, for the lack of a more precise term, "a principle or phenomenon of nature." The common thread throughout these cases is that claims which directly or indirectly preempt natural laws or phenomena are proscribed, whereas claims which merely utilize natural phenomena via explicitly recited manufactures, compositions of matter or processes to accomplish new and useful end results define statutory inventions.

In tracing this common thread, I will present not only extensive quotations from the bodies of the Court's opinions, but also the respective claims and avowed inventions. This assures that the Court's explanations are not taken out of context and are read with full knowledge of the fact patterns facing the Court in each case.

One of the first Supreme Court opinions to consider this concept of phenomena of nature was *O'Reilly v. Morse*, *supra*, which arose from Morse's claim to be the first inventor of the telegraph. The portion of the Court's long opinion which is relevant here is its consideration of the validity of Morse's 1840 patent which had been reissued in 1848. The reissued patent contained eight claims; the first, third, and eighth claims are as follows:

"First. Having thus fully described my invention, I wish it to be understood that I do not claim the use of the galvanic current, or current of electricity, for the purpose of telegraphic communications, generally; but what I specially claim as my invention and improvement, is making use of the

motive power of magnetism, when developed by the action of such current or currents, substantially as set forth in the foregoing description of the first principal part of my invention, as means of operating or giving motion to machinery, which may be used to imprint signals upon paper or other suitable material, or to produce sounds in any desired manner, for the purpose of telegraphic communication at any distances.

"The only ways in which the galvanic currents had been proposed to be used, prior to my invention and improvement, were by bubbles resulting from decomposition, and the action or exercise of electrical power upon a magnetized bar or needle; and the bubbles and deflections of the needles, thus produced, were the subjects of inspection, and had no power, or were not applied to record the communication. I therefore characterize my invention as the first recording or printing telegraph by means of electro-magnetism.

"There are various known modes of producing motion by electro-magnetism, but none of these had been applied prior to my invention and improvement, to actuate or give motion to printing or recording machinery, which is the chief point of my invention and improvement.

"Third. I also claim, as my invention and improvement, the combination of machinery herein described, consisting of the generation of electricity, the circuit of conductors, the contrivance for closing and breaking the circuit, the electro-magnet, the pen or contrivance for marking, and the machinery for sustaining and moving the paper, altogether constituting one apparatus of telegraphic machinery, which I denominate the American Electro-Magnetic Telegraph.

"Eighth. *I do not propose to limit myself to the specific machinery, or parts of machinery, described in the foregoing specifications and claims; the essence of my invention being the use of the motive power of the electric or galvanic current,*

which I call electro-magnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer." [Emphasis ours. *Id.* at 84-5.]

The Court perceived a clear distinction between claim 8, wherein Morse attempted to escape any apparatus limitations on his invention, and the preceeding seven claims, and stated:

We perceive no well-founded objection to the description which is given of the whole invention and its separate parts, nor to his right to a patent for the first seven inventions set forth in the specification of his claims. The difficulty arises on the eighth.

* * * * *

It is impossible to misunderstand the extent of this claim. He claims the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance.

If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Nor is this all, while he shuts the door against inventions of other persons, the patentee would be

able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light. For he says he does not confine his claim to the machinery or parts of machinery, which he specifies; but claims for himself a monopoly in its use, however developed, for the purpose of printing at a distance. New discoveries in physical science may enable him to combine it with new agents and new elements, and by that means attain the object in a manner superior to the present process and altogether different from it. And if he can secure the exclusive use by his present patent he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery, upon the records of the patent office. And when his patent expires, the public must apply to him to learn what it is. In fine he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of opinion that the claim is too broad, and not warranted by law. [Footnotes omitted. *Id.* at 112-3.]

Although the Court did not use the words "phenomenon of nature," it is apparent that claim 8 was held improper because by disclaiming all apparatus limitations, Morse was attempting to define the limits of his invention in terms of the natural phenomenon of electromagnetism and would, therefore, preempt the use of this phenomenon. The remaining claims, however, defined particular manufactures which employed the same phenomenon to accomplish new and useful end results. The Court voiced no objection to these claims.

Preceding *O'Reilly v. Morse*, the Court decided *Le Roy v. Tatham*, *supra*. The invention in *Le Roy* concerned the manufacture of lead pipes. Evidently, at the time of Le Roy's invention, lead pipes were made by casting the pipe in pieces and then welding the pieces together. Pipes manufactured in this manner had the

undesirable characteristic of leaking at the welds. The pipe made by Le Roy differed in that it was wrought by heat, pressure and constriction from solidified metal and not by casting in a mold. Le Roy and his coinventor claimed their invention as follows:

"We do not claim as our invention and improvement, any of the parts of the above-described machinery, independently of its arrangement and combination above set forth. What we do claim as our invention, and desire to secure, is, the combination of the following parts above described, to wit: the core and bridge, or guide-piece, with the cylinder, the piston, the chamber and the die, when used to form pipes of metal, under heat and pressure, in the manner set forth, or in any other manner substantially the same." [*Id.* at 172.]

The controversy before the Court arose from an alleged infringement of the claim, and specifically at issue was the following instruction by the lower court to the jury:

[T]he originality [of Le Roy's invention] did not consist in the novelty of the machinery, but in bringing a newly discovered principle into practical application, by which a useful article of manufacture is produced, and wrought pipe made as distinguished from castpipe. [*Id.* at 174.]

In discussing the claim in view of the jury instruction, the Court made the following statements concerning why natural phenomena, per se, are not proper subjects for patents and then discoursed on the types of discoveries and inventions that are properly subject to patenting:

The word *principle* is used by elementary writers on patent subjects, and sometimes in adjudications of courts, with such a want of precision in its application, as to mislead. It is admitted, that a principle is not patentable. A principle, in the

abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known. Through the agency of machinery a new steam power may be said to have been generated. But no one can appropriate this power exclusively to himself, under the patent laws. The same may be said of electricity, and of any other power in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.

In all such cases, the processes used to extract, modify, and concentrate natural agencies, constitute the invention. The elements of the power exist; the invention is not in discovering them, but in applying them to useful objects. Whether the machinery used be novel, or consist of a new combination of parts known, the right of the inventor is secured against all who use the same mechanical power, or one that shall be substantially the same.

A patent is not good for an effect, or the result of certain process, as that would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws.

A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable; but the process through which the new property is developed and applied, must be stated, with such precision as to enable an ordinary mechanic to construct and apply the necessary process. This is required by the patent laws of England and of the United States, in order that when the patent shall run out, the public may know how to profit by the invention. It is said, in the case of the *Househill Company v. Neilson*, 1 Webs. Pat. Cas. 683, "A patent will be good, though the subject of the patent consists in the discovery of great, general, and most comprehensive principle in science or law of

nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained." [*Id.* at 174-5.]

The Court held that the jury instruction was erroneous because a combination of machinery was indeed claimed, and "[t]he question whether the newly-developed property of lead, used in the formation of pipes, might have been patented, if claimed as developed, without the invention of machinery, was not in the case." *Id.* at 176. Thus, although the Court recognized that Le Roy's invention was based upon and implemented a newly discovered but naturally occurring phenomenon of lead, the claim did not directly or indirectly preempt the phenomenon because it was expressly limited to the claimed apparatus.

The Supreme Court next addressed the patentability of a natural phenomenon in *Tilghman v. Proctor*, supra. This case concerned an alleged infringement of Tilghman's patent for a process of separating fats and oils into their component parts. In particular, Tilghman had discovered that a desirable separation could be accomplished by mixing the fats and oils with water and then subjecting the mixture to high pressures at high temperatures. Tilghman's patent claim reads as follows:

Having now described the nature of my said invention, and the manner of performing the same, I hereby declare that I claim, as of my invention, the manufacturing of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure. [*Id.* at 709.]

The accused infringer argued that Tilghman's patent was invalid because it claimed a natural phenomenon, i.e., that heat, water and pressure can dissolve fat.

In addressing this argument, the Court distinguished between Tilghman's discovery and his claims:

What did Tilghman discover? And what did he, in terms, claim by his patent? He discovered that fat can be dissolved into its constituent elements by the use of water alone under a high degree of heat and pressure; and he patented *the process* of "manufacturing fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure." [*Id.* at 721. Emphasis in original.]

The Court next considered the proper interpretation of *O'Reilly v. Morse*, *supra*, and the effect of that decision on the patentability of machines and processes which employ natural phenomena to produce new and useful results. The Court stated:

We think that a careful examination of the judgment in that case will show that nothing adverse to patents for processes is contained in it. The eighth claim of Morse's patent was held to be invalid, because it was regarded by the court as being not for a process, but for a mere principle. It amounted to this, namely, a claim of the exclusive right to the use of electro-magnetism as a motive power for making intelligible marks at a distance; that is, a claim to the exclusive use of one of the powers of nature for a particular purpose. It was not a claim of any particular machinery, nor a claim of any particular process for utilizing the power; but a claim of the power itself,—a claim put forward on the ground that the patentee was the first to discover that it *could* be thus employed. This claim the court held could not be sustained. [*Id.* at 726-7. Emphasis in original.]

The Court continued by quoting the *Morse* opinion as follows:

After reviewing the statutes and decisions bearing upon the subject, the Chief Justice makes a summary conclusion of the whole matter, as follows: "Whoever discovers that a certain useful result will be produced, in any art, machine, manufacture, or

composition of matter, by the use of certain means, is entitled to a patent for it; provided he specifies the means he uses in a manner so full and exact that any one skilled in the science to which it appertains can, by using the means he specifies, without any addition to or subtraction from them produce precisely the result he describes. And if this cannot be done by the means he describes, the patent is void. And if it can be done, then the patent confers on him the exclusive right to use the means he specifies to produce the result or effect he describes, and nothing more. And it makes no difference, in this respect, whether the effect is produced by chemical agency or combination; or by the application of discoveries or principles in natural philosophy, known or unknown before his invention; or by machinery acting altogether upon mechanical principles. In either case, he must describe *the manner or process* as above mentioned, and the end it accomplishes. And any one may lawfully accomplish the same end without infringing the patent, if he uses means substantially different from those described." [*Id.* at 727 quoting 15 How. at 118-9. Emphasis in original.]

In applying these principles to Tilghman's claim, the Court stated:

In the first place, the claim of the patent is not for a mere principle. The chemical principle or scientific fact upon which it is founded is, that the elements of neutral fat require to be severally united with an atomic equivalent of water in order to separate from each other and become free. This chemical fact was not discovered by Tilghman. He only claims to have invented a particular mode of bringing about the desired chemical union between the fatty elements and water. He does not claim every mode of accomplishing this result. [*Id.* at 729.]

Since the Court did not find the claim to monopolize the natural phenomenon, the claim was held valid.

In *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, supra, the Court considered the validity of a patent for an improved apparatus for making newspaper stock. The patentee, Eibel, discovered that the speed of a well-known papermaking machine could be significantly increased by employing the force of gravity. This was accomplished by elevating one end of the device so that the flow rate of the stock would be increased by causing it to flow downhill. Claim 1 is representative of the claims in the patent, and reads:

1. A Fourdrinier machine having the breast-roll end of the paper-making wire maintained at a substantial elevation above the level, whereby the stock is caused to travel by gravity, rapidly, in the direction of movement of the wire, and at a speed approximately equal to the speed of the wire, substantially as described. [*Id.* at 50.]

The validity of the claims was not challenged on the grounds that they improperly monopolized the natural phenomenon of gravity and the case is often cited approvingly as an example of the proper use of a natural phenomenon to produce a new and useful end result. See *Parker v. Flook*, supra.

The Court next considered a patent based upon a natural phenomenon in *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, supra, which concerned the alleged infringement of a number of patents. One of the patents alleged to be infringed was for an antenna system which utilized principles of electromagnetic wave propagation and the phenomenon of standing waves to produce new and useful results. The phenomenon was describable by a mathematical formula which appeared in the claims as follows:

15. An antenna comprising a pair of relatively long conductors disposed with respect to each other at an angle substantially equal to twice

degrees, ι being the length of the wire and λ the operating wave length in like units, and means in circuit with said antenna for exciting the conductors in phase opposition whereby standing waves of opposite instantaneous polarity are formed on the conductors throughout their length. [*Id.* at 96, n.4.]

The formula expressed the physical relationship of two conductors in the assembled antenna. That the Court considered this to be a proper claim to the use of a natural phenomenon and not a preemption of the phenomenon itself, is evident from the following passage from the opinion:

While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be * * * We assume * * * that this advance was invention even though it was achieved by the logical application of a known scientific law to a familiar type of antenna. But it is apparent that if this assumption is correct the invention was a narrow one, consisting of a structure conforming to the teachings of the Abraham formula as to angle and wire length relative to wave length, and is to be strictly construed with regard both to prior art and to alleged infringing devices. [*Id.* at 94.]

In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, supra, the Court considered the validity of a patent to one Bond and the alleged infringement of a number of the patent's product claims. The subject matter involved certain naturally occurring bacteria of the genus *Rhizobium* which infect the roots of leguminous plants and form nodules thereon hence enabling the plants to transform atmospheric nitrogen into organic nitrogenous compounds necessary for plant growth. It was well known that each species of these naturally occurring bacteria would only infect certain species of

leguminous plants. Attempts (prior to Bond's work) to produce a useful mixture of bacteria, which farmers could use upon planting more than a single variety of plant, were unsuccessful. When mixed, different species of *Rhizobium* bacteria exhibited a mutually inhibiting effect and no suitable mixture had, therefore, been produced. Bond discovered that certain strains of the bacteria were not mutually inhibitive and he produced mixtures of the *Rhizobium* bacteria which mixtures were capable of inoculating multiple varieties of plants. Bond was granted a patent on his discovery. The Supreme Court found the following claim to be representative of Bond's invention:

An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific. [*Id.* at 128, n.1.]

Justice Douglas, speaking for a majority of the Court, said the following about Bond's claimed invention:

We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. Bond does not create a state of inhibition or of noninhibition or of *noninhibition* in the bacteria. Their qualities are the work of nature. Those qualities are of-course not patentable. For patents cannot issue for the discovery of the phenomena of nature. See *Le Roy v. Tatham*. 14 How. 156, 175. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the

law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end. See *Telephone Cases*, 126 U.S. 1, 532-533; *DeForest Radio Co. v. General Electric Co.*, 283 U.S. 664, 684-655; *Mackay Radio & Tel. Co. v. Radio Corp.*, 306 U.S. 86, 94, *Cameron Septic Tank Co. v. Saratoga Springs*, 159 F. 453, 462-463. The Circuit Court of Appeals thought that Bond did much more than discover a law of nature, since he made a new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants. But we think that aggregation of species fell short of invention within the meaning of the patent statutes.

Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one produce is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. *The combination of species produces no new bacteria, no change in the six species of bacteria and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.* [*Id.* at 130-1. Emphasis added.]

The Court held that "the product claims do not disclose an invention or discovery within the meaning of the patent statute." *Id.* at 132. This holding appears to arise, in part, from Bond's manner of claiming his invention, i.e., in terms of its property—non-inhibition—instead of claiming the precise constituent elements of his mixtures. The effect is an indirect, but nonetheless effective, monopoly over the phenomenon because the test for inclusion of a strain within the claim limits is the existence of the phenomenon.³

Although the Supreme Court has considered the question of patentable subject matter in other cases both before and after the 1952 Act, *see e.g.*, *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673 (1972), the cases cited above comprise the precedential background of the Court's decision in *Parker v. Flook*, *supra*, and they trace the development of the judicial proscription on the patentability of purely natural phenomenon.

In *Flook*, the applicant presented claims to a method for computing and updating certain alarm limits critical

³Both *Funk* and *Cameron Septic Tank Co. v. Saratoga Springs*, 159 F. 453 (2d Cir. 1908), (cited approvingly in *Funk*, 333 U.S. at 130), concerned patents which involved living bacteria. The fact that the bacteria were alive was not raised as a grounds for invalidity in either case. In both cases, however, the patents were challenged on the basis that they improperly monopolized natural phenomena. The identified phenomenon in each case was that which made the claimed bacteria valuable to the patentees. In *Funk*, the phenomenon was the mutual noninhibition of certain bacteria and in *Cameron* the phenomenon was the effect of the bacteria on effluent.

It might be observed that paragraph three of 35 USC 112 currently provides for "means plus function" elements as part of so-called "combination" claims. Although Bond used such a claim form in his patent, the Supreme Court considered the claims to effectively preempt the complete "non-inhibitive" biological function which Bond had discovered in nature. Clearly "means plus function" claims can be patentable even when the function is a naturally occurring one—note Morse's claims 1 and 3, *supra*—but care must be taken so as not to preclude *all* of the natural phenomenon utilized by the "means" in those claims.

to the catalytic conversion process of hydrocarbons. The essential feature of the process as claimed was a new mathematical formula for computing the values of the alarm limits from certain input quantities. The Court indicated that a formula is similar to a principle or law of nature and it quoted from the *Benson* opinion:

"A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. *Le Roy v. Tatham*, 14 How. 156, 175. Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work. [437 U.S. at 589, 198 USPQ at 197, quoting 409 U.S. at 67, 175 USPQ at 675.]

The Court in *Flook* continued its analysis by stating that "[t]he rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of "discoveries" that the statute was enacted to protect." 437 U.S. at 593, 198 USPQ at 198. The Court did, however, identify certain circumstances wherein claims encompassing natural phenomena define statutory subject matter when it stated "[e]ven though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application." *Id.* at 594, 198 USPQ at 199.

The invention under consideration in *Flook* is exemplified by claim 1:

1. A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemi-

cal conversion of hydrocarbons wherein said alarm limit has a current value of

$$B_0 + K$$

wherein B_0 is the current alarm base and K is a predetermined alarm offset which comprises:

- (1) Determining the present value of said process variable, said present value being defined as PVL;
- (2) Determining a new alarm base B_1 , using the following equation:

$$B_1 = B_0(1.0 - F) + PVL(F)$$

where F is a predetermined number greater than zero and less than 1.0;

- (3) Determining an updated alarm limit which is defined as $B_1 + K$; and thereafter

- (4) Adjusting said alarm limit to said updated alarm limit value.

[*Id.* at 596-7, 198 USPQ at 200.]

Examining this claim in view of the Court's statements in *Flook* and the cases discussed above makes it clear that the Court considered the allowance of such a claim to be a preemption of the formula or natural principle recited therein because the non-computation steps merely gather values necessary for the computation or employ the computed results in the only manner in which they are useful. The result would be a patent on the principle, i.e., the formula or method of calculation, and the Court held that such a method of calculation was not a process within the meaning of 35 USC 101. *Id.* at 595, n.18, 198 USPQ at 199, n.18.

In each of the aforementioned cases, the Supreme Court centered its analysis on the phenomenon which made the invention valuable to the inventor and then proceeded to determine whether or not the inventor attempted to preclude others from using those bare phenomena.

So, in the appeals at hand, the initial consideration should be into the respective discoveries and the natu-

ral phenomena involved, followed then by an assessment of the scope of the claims with regard to those phenomena.

Considering, first, the Bergy appeal: The invention therein centers on the discovery that certain microorganisms have the distinctly useful property of producing the antibiotic lincomycin. The phenomena involved in making the invention valuable to the inventor are those only dimly understood, but nevertheless existing, metabolic processes leading to the noted drug. Do Bergy and his coinventors attempt to preempt all others from the biological production of lincomycin? I think it clear that they do not. The claim in issue:

A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

is limited to but a single microorganism, which, in its claimed form,⁴ does not even occur in nature. Indeed,

⁴As adequately demonstrated in affidavits submitted by appellants, this microorganism, in the condition as it is found in Arizona soil, does not produce lincomycin.

Parenthetically, the PTO follows well-established case law in dropping the product-of-nature rejection regarding this claim. Several courts, including this one, have considered the patentability of purified naturally occurring products and found them generally to be within the purview of §101 or its predecessors. See *In re Bergstrom*, 57 CCPA 1240, 427 F.2d 1394, 166 USPQ 256 (1970) (prostaglandin compounds), *Merck v. Olin Mathieson Chemical*, 253 F.2d 156, 116 USPQ 484 (4th Cir. 1958) and *Merck v. Chase Chemical*, 273 F. Supp. 68, 155 USPQ 139 (D.N.J. 1967) (Vitamin B-12); *Sterling Drug v. Watson*, *Comr. Pats.*, 135 F. Supp. 173, 108 USPQ 37 (D.C.D.C. 1955) (1-arterenol); *Parke-Davis v. Mulford*, 196 F. 496 (2d Cir. 1912) (adrenalin).

the Bergy et al. patent application specifically discloses at least four other microorganisms used to biologically produce the drug.

The invention of Chakrabarty revolves around the abilities of certain bacteria to digest or metabolize various hydrocarbon components of crude oil. Again, these capabilities are natural phenomena and occur via complex metabolic processes.

Chakrabarty's broadest claims:

7. A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

21. An inoculum for the degradation of a pre-selected substrate comprising a complex or mixture of hydrocarbons, said inoculum consisting essentially of bacteria of the genus *Pseudomonas* at least some of which contain at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

do not preempt the biological metabolism of hydrocarbons. As in the Bergy et al. application, the microorganisms as claimed by Chakrabarty cannot be found in nature, and the results producible with the claimed microorganism are not duplicated in nature. Also, Chakrabarty points out that a number of the member of the genus *Pseudomonas* have the ability to metabolize specific types of hydrocarbons, and, thus, provide other available means capable of providing (albeit, not as effectively) similar functions.⁵

⁵Chakrabarty discloses that bacterial mixtures have been used to metabolize crude oils. However, because of the disparate nutritional requirements and growth rates of the component single-plasmid species, the effectiveness of these mixtures was not exceptional. By providing multiple plasmids in the single microorganism, Chakrabarty obviates these problems.

In sum, it seems quite clear that the claims in both of these appeals do not reach out to encompass natural phenomena as did Morse's claim 8 or the claims in *Funk*, but rather recite only non-naturally occurring compositions of matter that are but single tools for utilizing natural phenomena in producing new and useful end results.

Having completed the task suggested by the Supreme Court in its remand, a few general comments are in order.

The PTO argues⁶ that "without a 'clear and certain' signal that it [Congress] intended living organisms—not to mention microorganisms—to be patentable subject matter under 35 USC 101," we should not attempt to extend the scope of that section. As should be apparent from my earlier comments, supra n.1 and accompanying text, I do not view the patenting of microorganisms⁷ as an extension of the broadly intended §101 as long as the scope of the patent monopoly does not fall within the areas proscribed by the Supreme Court in the cases discussed above.

This improvement in effectiveness and my view that living things are patentable (see n. 3, supra) now lead me to the conclusion that even under the analysis provided in *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 8 *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 8 USPQ 131 (1930), the claimed microorganism is a "manufacture" within the meaning of the statute.

⁶Supplemental brief of the PTO, citing *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531, 173 USPQ 769, 774 (1972).

⁷As a practical matter, I do not foresee the patenting of higher forms of life because of the inherent difficulty in complying with the enablement provisions of 35 USC 112, paragraph one. Microorganisms are probably a special case because of their ease of description, see *In re Argoudelis*, 58 CCPA 769, 434 F.2d 1390, 168 USPQ 99 (1970), and the apparent availability of samples of the microorganisms, themselves, from one of the various culture depositories.

Finally, the Plant Patent Act appears to voice both the recognition and the reaction of Congress to the fact that some new varieties of plants were no longer merely products of nature, but were also the products of man. The House Report on the Plant Patent Act evidences this Congressional recognition in stating:

[A] plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man, and such discoveries can only be made available to the public by encouraging those who own the single specimen to reproduce it asexually and thus create an adequate supply.

It is obvious that nature originally creates plants but it can not be denied that man often controls and directs the natural processes and produces a desired result. In such cases the part played by nature and man can not be completely separated or weighed or credited to one or the other. Nature in such instances, unaided by man, does not reproduce the new variety true to type. [8]

A memorandum from the Commissioner of Patents, then Thomas E. Robertson, to the Secretary of Commerce, R. P. Lamont, shows that it was this difficulty in providing sufficient description of to-be-patented plants, and not the fact that plants are alive which precluded their patenting under the then-current statute:

Further, and more important, there at once arises the difficulty of defining in a written document which must be printed, both as constituting part of the patent and as constituting a publication available for search and distribution, the differences which identify a new variety from previously known varieties. For example, if that difference exists only in the color of the bloom, then in order to describe that difference it would seem that a colored print of some sort would have to constitute a part of the patent.

⁸H. R. Rep. No. 1129, 71st Cong., 2d Sess. 7 (1930).

If it is not possible by ordinary description of the physical qualities of the plant, or the fruit, or the bloom, or all three, to so accurately define this new variety that it can be differentiated from all known varieties and from all subsequently created new varieties, then it is difficult to see how a patent to be granted would comply with the other provisions of the statutes, namely, that the inventor must describe his invention in full, clear, concise, and exact terms. (R.S. 4888.)

In other words, section 4888, Revised Statutes, requires one who obtains a patent to file in the Patent Office "a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains * * * to make, construct, compound, and use the same."

In many instances (if not all) it may be found that no description could be written that would enable any one to identify so as to reproduce from that description (without the extraneous aid of physical cuttings or slips grafted in accordance with the usual methods) the new variety, as the only way asexually reproduced varieties can be reproduced is from a physical cutting or slip from the new variety itself. To state the matter in another way, if after the new variety were produced, and then reproduced asexually, an application for patent was filed with the most explicit description that it is possible to furnish, and all the plants containing such a new species were destroyed, as for example by fire, then there would be no way whatever of reproducing this new species. The written, description filed in the Patent Office would be useless and hence could not satisfy the conditions of section 4888, Revised Statutes. [9]

⁹A Bill to Provide for Plant Patents: Hearings on H.R. 11372 before the Comm. on Patents, 71st Cong., 2d Sess. 7 (1929-30) (statement of Hon. Fred S. Purnell).

The reaction of Congress was the relaxation of the description requirement as a means for constitutionally "promoting" the "useful art" of plant breeding. The bill, as passed, included the provision "[n]o plant patent shall be declared invalid on the ground of non-compliance with this section [§4888-35 USC 33 (1930)] if the description is made as complete as is reasonably possible."

Additionally, both the Senate and the House directly considered the question of the constitutionality of granting patents on plants and both concluded:

[T]he amendments to the patent laws proposed by the bill fall within the legislative power of Congress under Article I, section 8, of the Constitution—

* * * * *

There can be no doubt that the grant of plant patents constitutes a promotion of "the progress of science and useful arts" within the meaning of the constitutional provision. [10]

In sum, the legislative history of the Plant Patent Act, and its virtual lack of constitutional challenge throughout the following 50 years demonstrate that living things are patentable under the Constitution. The intended breadth of §101 provides a similar conclusion under the Patent Act of 1952 if the statutory description requirements can be satisfied. Finally, my examination of the claimed inventions reveals them to be exterior to the judicially defined areas of *unpatentable* subject matter. Accordingly, I would reverse the decisions of the board.

¹⁰H.R. Rep. No. 1129, 71st Cong., 2d Sess. 7 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 6 (1930).

UNITED STATES COURT OF COSTOMS
AND PATENT APPEALS

Appeal No. 76-712.
Serial No. 477,766.

IN THE MATTER OF THE APPLICATION
OF

MALCOLM E. BERGY, JOHN H. COATS,
and VEDPAL S. MALIK

IN THE MATTER OF THE APPLICATION
OF

ANANDA M. CHAKRABARTY

Appeal No. 77-535.
Serial No. 260-563.
IN THE MATTER OF THE APPLICATION

OF

ANANDA M. CHAKRABARTY

Before MARKEY, Chief Judge, RICH, BALDWIN, LANE,
and MILLER, Associate Judges.

MILLER, Judge, dissenting.

I do not share the majority's conclusion that the Supreme Court's opinion in *Parker v. Flook*, 437 U.S. 584, 198 USPQ 193 (1978), sheds no light on these cases. By concentrating on the literal statements of the Court, including the Court's quotation from its opinion in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531, 172 USPQ 769, 774 (1972), the majority has missed the essential thrust of the Court's opinion that, recognizing that Congress could not foresee all new developments in technology and that 35 USC 101 should be broadly construed, *where there is a basis for substantial doubt over the intent of Congress* regarding the breadth of the language in the statute, the Court will await a "clear and certain signal from Congress" on the subject.

I submit that a basis for substantial doubt, at least, exists over whether organisms (or microorganisms) developed by inventors were intended by Congress to be embraced by the words "manufacture" or "composition of matter." Previously stated¹ are my reasons for believing that the Plant Patent Act of 1930 [ch. 312, 46 Stat. 376] and the Plant Variety Protection Act of 1970 [84 Stat. 1542], along with their accompanying legislative history, clearly establish that Congress did *not* intend that *any* organisms (which would include microorganisms), other than the plants² covered by those Acts, be within the scope of 35 USC 101.

If Congress intended otherwise, there would have been no need to enact such legislation, and there is a basic presumption that Congress does not legislate un-

¹ In my dissenting opinions in *In re Chakrabarty*, 571 F.2d 40, 45, 197 USPQ 72, 76 (CCPA), cert. dismissed sub nom. *Banner v. Chakrabarty*, 99 S. Ct. 44 (1978), and in *In re Bergy*, 563 F.2d 1031, 1039, 195 USPQ 344, 351 (CCPA 1977), vacated and remanded sub nom. *Parker v. Bergy*, 438 U.S. 902, 198 USPQ 257 (1978).

² As defined by Webster's *Third New International Dictionary* 1731 (unabr. 1971), a plant is "any of numerous organisms constituting the kingdom Plantae." (Emphasis added).

necessarily. See *Platt v. Union Pacific Railroad*, 99 U.S. 48, 58 (1878); *In re Finch*, 535 F.2d 70, 71, 190 USPQ 64, 65 (CCPA 1976); *United States v. C.J. Tower & Sons*, 44 CCPA 1, 5, C.A.D. 626 (1956); *Skovgaard v. The M/V Tungus*, 252 F.2d 14, 17 (CA 3 1957), aff'd, 358 U.S. 588 (1959); *United States v. Korpan*, 237 F.2d 676, 680 (CA 7 1956), rev'd on other grounds, 354 U.S. 271 (1957). Both the majority and concurring opinions fail to point to anything that would rebut that presumption.

The majority and concurring opinions stress *one* aspect of the 1930 Act, namely: under then-existing law it was not seen how a plant could be described in a written document to comply with the "written description" requirement of section 4888 of the Revised Statutes (now 35 USC 112), and so the substance of what is today the first sentence of 35 USC 162 was added to the law. However, this addition to the law was merely ancillary to the extension of the patent law to plant inventions by the provision of what is today 35 USC 161 ("Patents for Plants"). And it is to the extension of the patent law that the above-stated basic presumption applies—a point which the majority and concurring opinions fail to address. The 1930 Act amended section 4886 of the Revised Statutes to read:

Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter or any new and useful improvements thereof, *or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber propagated plant * * ** may, upon payment of the fees required by law, and other due proceeding had, obtain a patent therefor. [Additional matter underscored.]

Section 4892 of the Revised Statutes was amended to read:

The applicant shall make oath that he does verily believe himself to be the original and first inventor

or discoverer of the art, machine, manufacture, composition, or improvement, *or of the variety of plant*, for which he solicits a patent; that he does not know and does not believe that the same was ever before known or used; and shall state of what country he is a citizen [Additional matter underscored.]

The 1930 Act also amended the section 4884 of the Revised Statutes, singling out asexually reproduced plants for patent protection. If Congress had intended the words "manufacture" or "composition of matter" in sections 4886 and 4892 of the Revised Statutes and their predecessors to embrace organisms (or microorganisms), enactment of the above amendments would have been unnecessary. The same basic presumption applies with respect to enactment of a 1954 amendment to Section 161 (ch. 1259, 68 Stat. 1190)³ and with respect to enactment in 1970 of the Plant Variety Protection Act. Thus, the majority and concurring opinions are forced into the untenable position of maintaining that Congress—not once, but thrice—enacted needless legislation.⁴

³The purpose of this amendment was to "remove any doubt that the legislative intent of the Congress clearly means that sports, mutants, hybrids, and seedlings, discovered by persons engaged in agriculture or horticulture, should be patentable." H.R. Rep. No. 1455, 83rd Cong., 2d Sess. (1954); S. Rep. No. 1937, 83d Cong., 2d Sess. (1954).

⁴Both the Senate Judiciary Committee report (S. Rep. No. 91-1246, 91st Cong., 2d Sess. 3 (1970)) and the House Committee on Agriculture report (H.R. Rep. No. 91-1605, 91st Cong., 2d Sess. 1 (1970)) accompanying the bill (S. 3070) which became the Plant Variety Protection Act stated:

Under patent law, protection is presently *limited* to those varieties of plants which reproduce asexually, that is, by such methods as grafting or budding. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection

The majority opinion emphasizes that the Plant Patent Act was concerned only with plants. This completely misses the point. If section 4886 of the Revised Statutes did, indeed, embrace organisms (and microorganisms), then why would Congress needlessly legislate coverage for organisms known as "plants"?

In both the House and Senate Committee Reports accompanying the bills that became the Plant Patent Act,⁵ after quoting from the then-existing patent laws as applying to "any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof," the following statement appears:

There is a clear and logical difference between the discovery of a new variety of plant and of certain *inanimate* things, such, for example, as a new and useful natural mineral.

* * * * *

Furthermore, there is no apparent difference, for instance, between the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter which are patentable under existing law. Obviously, these new compositions of matter do not come into being solely by act of man. The chemist who invents the composition of matter must avail himself of the physical and chemical qualities inherent in the materials used and of the natural principles applicable to the mat-

is *not* available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans. [Emphasis added.]

Thus, the Patent Act of 1952, as amended in 1954, was considered to cover only plants falling under 35 USC 161, and 35 USC 101 was obviously considered to cover no plants or other organisms whatsoever.

⁵H.R. Rep. No. 1129, 71st Cong., 2d Sess. 7-8 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 6-8 (1930).

ter. . . . The same considerations are true of the plant breeder. He avails himself of the natural principles of genetics and of seed and bud variations.

* * * * *

But even were the plant developer's contributions in aid of nature less creative in character than those of the chemist in aiding nature to develop a *composition of matter* which has theretofore been nonexistent . . . nevertheless the protection by patents of those engaged in plant research and discovery would not be beyond the constitutional power of Congress. [Emphasis added.]

Thus, Congress recognized the dichotomy of animate and inanimate inventions and decided to extend patent protection for animate inventions, but only to asexually reproduced plants.⁶ The nature of organisms, whether microorganisms, plants, or other living things, is fundamentally different from that of inanimate chemical compositions.

Accompanying the hearings on the proposed plant patent legislation was a letter from the Commissioner of Patents expressing some doubt over the constitutionality of providing for a patent grant on a new plant variety, when the plant is reproduced by operation of nature, aided only by the act of the patentee in grafting it by usual methods. The committee reports, stating that "the protection by patents of those engaged in plant research and discovery would not be beyond the constitutional power of Congress," show that Congress did not share the Commissioner's doubt.⁷ The Commis-

⁶ See *In re LeGrice*, 49 CCPA 1124, 1139, 301 F.2d 929, 939, 133 USPQ 365, 374 (1962).

⁷ The same doubt was expressed by the Commissioner regarding the 1954 amendment to section 161, *supra*. This was rejected in the accompanying committee reports, *supra* note 3, which stated that "the committee is of the opinion that this type of legislation does have constitutional basis for its enactment."

sioner's recommendation that the legislation take the form of a supplement to section 4886 was not adopted, as can be seen from the amended sections 4886 and 4892 quoted earlier in this opinion.

It is true that, as the majority opinion states, the Plant Patent Act was enacted *after* section 4886 of the Revised Statutes had been enacted, and that this is not as strong evidence of Congressional intent underlying section 4886 as contemporaneous enactment would have been. However, such subsequently enacted legislation is, nonetheless, entitled to "great weight in statutory construction." *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-81 (1969); *Glidden Co. v. Zdanok*, 370 U.S. 530, 541 (1962). More importantly, when the patent law, including section 4886, was codified by the Patent Act of 1952 [ch. 950, 66 Stat. 792] into title 35 of the United States Code, the statutory law, judicial precedent, and legislative intent (including that expressed in connection with the Plant Patent Act of 1930) were all carried forward into the codification.⁸ See *Fourco Glass Co. v. Transmirra Corp.*, 353 U.S. 222 (1957); 82 C.J.S. *Statutes* § 276 (1953). See also *Muniz v. Hoffman*, 422 U.S. 454, 469 (1975). As well stated in 1A *Sands, Sutherland Statutes and Statutory Construction* § 28.10 at 327 (4th ed. 1972):

In case of ambiguity it is permissible to resort to the prior legislative history of the act, the form and language of the prior statute, prior interpretation, other legislation in *pari materia* and *all pertinent aids to statutory construction in order to arrive at the true meaning of the code provision*. [Footnote omitted.]

The majority and concurring opinions refer to a comment in the committee reports accompanying the bill

⁸ It should be noted that no such carryover of legislative intent into a codification was present in *Rainwater v. United States*, 356 U.S. 590 (1958), cited in the majority opinion.

that became the Patent Act of 1952, that, with reference to section 101, "a machine, or a manufacture . . . may include *anything under the sun that is made by man*." (Emphasis added). However, they neglect to point out that this must be read in light of the *later* comment that the "next chapter collects the provisions relating to plant patents," which in itself indicates that "anything under the sun that is made by man" is not to be taken literally.⁹ This court assuredly did not take the comment literally in its opinion ten years later in *In re LeGrice*, *supra* at 1139, 301 F.2d at 939, 133 USPQ at 374, which recognized that under the Plant Patent Act of 1930—

The patent law, as shown by the Committee Reports, was *extended* to plant patents in order to stimulate interest in the breeding and commercial development of new and valuable plant species. [Emphasis added.]

If the patent law prior to the Patent Act embraced organisms, there would have been no reason for *extending* it to plant inventions.

The majority opinion says:

In short, we think the fact that microorganisms are alive is a distinction without legal significance and that they should be treated under § 101 no differently from chemical compounds.

* * * * *

. . . we do not see the logic of allowing claims to processes which depend for their operation on a living organism while denying claims to the organism or a pure culture of it *merely* because it is alive.

⁹The approach of the majority opinion here appears to be of the kind that Justices Jackson and Frankfurter (quoted in the majority opinion) criticized.

Those are arguments to be presented to the Congress—not to the Court.¹⁰ Then, perhaps, a "clear and certain signal" will come from the Congress, which assuredly has the constitutional power to extend the patent law to organisms other than plants. As well articulated by Chief Judge Markey in his concurring opinion in *In re McKellin*, 529 F.2d 1324, 1333, 188 USPQ 428, 437 (CCPA 1976):

[T]he patent law is statutory. Our representative form of government requires that the enactments of its Congress must always be, at the very least, the starting point. There being no common law of patents, we should take care to fill the Holmesian interstices of the statute with judge-made law only under the gravest and most impelling circumstances.

For the above reasons and others set forth in my dissenting opinions referred to earlier, the decisions of the board should be affirmed.

¹⁰The majority opinion points to a *few* instances over the years when, among the hundreds of thousands of patents issued, the Patent and Trademark Office has granted patents to organisms or microorganisms. There is no evidence that these were ever brought to the attention of Congress. *Cf. Natural Resources Defense Council, Inc. v. NRC*, 582 F.2d 166, 171-72 (CA 2 1978), and citations therein. The Commissioner's actions in the cases before us clearly indicate his position that the grant of such patents arose from administrative error, and there is no showing that such administrative error formed a consistent pattern.

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APPENDIX B

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

MANDATE

No. 76-712

IN THE MATTER OF THE APPLICATION
OF

MALCOLM E. BERGY, JOHN H. COATS,
and VEDPAL S. MALIK

Serial No. 477,766

ON APPEAL from the Board of Appeals This CAUSE
having been heard and considered, it is ORDERED and
ADJUDGED: Reversed

DATED March 29, 1979

105a

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

MANDATE

No. 77-535

IN THE MATTER OF THE APPLICATION
OF

ANANDA M. CHAKRABARTY

Serial No. 260,563

ON APPEAL from the Board of Appeals This CAUSE
having been heard and considered, it is ORDERED and
ADJUDGED: Reversed

DATED March 29, 1979

APPENDIX C

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALSPatent Appeal No. 76-712
IN THE MATTER OF THE APPLICATION

of

MALCOLM E. BERGY, JOHN H. COATS, and
VEDPAL S. MALIK

Serial No. 477,766

DECIDED: OCTOBER 6, 1977

RICH, Judge.

This appeal is from the majority decision of the divided Board of Appeals (board) of the United States Patent and Trademark Office (PTO) affirming the rejection of claim 5 of application serial No. 477,766, filed June 10, 1974. We reverse.

The Invention

The subject of the application, which, when filed, had the noncommittal title "Process," is made clear from the Abstract of the Disclosure, which reads:

Microbiological process for preparing the antibiotic lincomycin at temperatures ranging from 18° C. to 45° C. using the newly discovered microorganism *Streptomyces vellosus*. The subject process advantageously results in the preparation of

lincomycin without the concomitant production of lincomycin B (4'-depropyl-4'-ethyl-lincomycin). The absence of lincomycin B production results in increased lincomycin recovery efficiency.

On demand of the examiner, the title was later changed to "Process for Preparing Lincomycin." The application was filed with four claims to such a *process* which the examiner allowed. By a preliminary amendment, filed before any action on the application but not reached by the examiner until his second action, claim 5 was added together with the attorney's statement that "Basis for claim 5 can be found throughout the disclosure." That claim reads:

5. A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

The designation "NRRL 8037" in claim 5 is elucidated by the following statement in the specification:

The Microorganism

The novel actinomycete used according to this invention for the production of lincomycin is *Streptomyces vellosus*. One of its strain characteristics is the production of lincomycin without the concomitant production of lincomycin B. Another of its strain characteristics is the production of comparable titers of lincomycin at a temperature of 28° C. and 45° C. A subculture of this living organism can be obtained upon request from the permanent collection of the Northern Regional Research Laboratories, Agricultural Research Services, U.S. Department of Agriculture, Peoria, Illinois, U.S.A. Its accession number in this repository is NRRL 8037.

The specification continues:

The microorganism of this invention was studied and characterized by Alma Dietz of the Upjohn Research Laboratory.

What follows that statement is an elaborate, highly technical, detailed description of the microorganism, including its type designation as "*Streptomyces vellosus* Dietz, sp.n.," occupying over ten pages of the printed specification, followed by exemplary descriptions of the production of lincomycin therefrom by fermentation processes and the recovery of the lincomycin produced by the fermentation.

The Rejection

No references have been cited against claim 5 because the novelty and unobviousness of the biologically pure culture claimed are not questioned. Neither has utility been questioned.

The examiner's sole ground of rejection of claim 5, as stated in his final rejection, was:

Claim 5 is rejected under 35 USC 101 as non-statutory subject matter. Claim 5 claims a product of nature (*Streptomyces vellosus* NRRL 8037). See *In re Mancy et al.* 182 USPQ 303 at page 306, second sentence before [4].

Appellants responded with a request to reconsider this rejection supported by affidavits of three Upjohn microbiologists, Dr. Joseph E. Grady, Dr. Thomas L. Miller, and "the well-known microbial taxonomist Alma Dietz," pointing out that the microorganism did not exist as a biologically pure culture in nature and asserting that such a culture is a "manufacture" under § 101, which reads:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement

thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

In so arguing, appellants made the point that the pure culture is "a product of a microbiologist." The examiner adhered to his position and appeal was taken to the board.

Since the only ground given by the examiner in support of his nonstatutory-subject-matter rejection was that the culture was a product of nature, that was the only point argued by appellants in their brief before the board, in which they cited a number of precedents for holding that a *pure* product could be patentable over a known impure product of similar kind.

The Examiner's Answer—only two pages of the printed record—merely summarized his product-of-nature position and cited two cases in addition to *In re Mancy*, supra, previously cited by him, namely, *Guaranty Trust Co. of New York v. Union Solvents Corp.*, 54 F.2d 400, 12 USPQ 47 (D. Del. 1931), *aff'd*, 61 F.2d 1041, 15 USPQ 237 (CA 3 1932), and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948). With reference to the cases cited by appellants as precedents for patenting *pure* materials, the examiner noted that they were all pure chemical compounds "as contrasted with the instant microorganism." He noted that the cases cited by him all "involve isolated or biologically pure microorganisms." Appellants replied briefly, taking exception to the last-quoted statement of the examiner

* * * since (1) none of the decisions cited, nor any known decision, has held that a "biologically pure culture" is unpatentable, and (2) there is no evidence that a "biologically pure culture" was in issue in any of the cited decisions.

On the issue thus framed, the case went to the board.

The Board Opinions

The opinion of the majority of the board is quite out of the ordinary. While it affirms the "decision" of the examiner, that is to say his *rejection* of claim 5, it wholly disregards his *reason* for rejecting it to the point of expressly declining to consider it. Instead, the board majority decided that claim 5 is not directed to statutory subject matter within the meaning of §101 because it is for "a living organism," an issue entirely new to the application at bar, so far as the record shows. The dissenting board member's opinion confirms in its first paragraph that that is, strictly, the basis of the majority's decision. Without stating a new ground of rejection was being made (*cf.* 37 CFR 1.196 (b)), the majority opinion commences its explanation of its reasoning as follows:

We have extensively researched prior court decisions for guidance to the question of whether or not a microorganism, being a living thing, is or is not within the realm of statutory patentable subject matter, but, other than possibly non-controlling dicta, have not found any case directly in point.

It is our view that 35 U.S.C. 101 must be strictly construed and, when so interpreted, precludes the patenting of a living organism. We reach this conclusion on the basis that only those categories of subject matter specifically enumerated in the statute are patentable and a living organism does not fall within the scope of any of those categories listed. An analogous result has been reached by the courts with respect to non-patentability of mental processes, printed matter or methods of doing business none of which are also expressly excluded by the indicated section of the statute, but neither can they be said or have been held to be included thereby.

The board majority opinion then makes two points in support of its conclusion that § 101 precludes patenting

anything living. The first is based on this court's decision in *In re Arzberger*, 27 CCPA 1315, 112 F.2d 834, 46 USPQ 32 (1940), that bacteria are not included in the plant patent provision of former Title 35 (then part of §4886 of the Revised Statutes, since 1952 separately treated in 35 USC 161-164), notwithstanding that they may be scientifically classified as plants, because Congress plainly did not intend them to be when, in 1930, it enacted the Plant Patent Act (46 Stat. 376). The case was concerned only with the plant patent statute and this court did not have before it any other issue, such as inclusion of bacteria in any other statutory category, appellant having applied for a "plant patent" on a bacterium. The second aspect of the board majority's supporting reasoning is fully stated in the following paragraph:

If we were to adopt a liberal interpretation of 35 U.S.C. 101 new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and cross-breeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. 161, such as tuber propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. 101. We do not believe that Congress intended 35 U.S.C. 101 to encompass any living organism, whether they be plants or microorganisms.

The dissenting board member, stating that he had reviewed all of the precedents cited by either side and others as well, many of which he discussed in detail, expressed these views:

* * * I do not believe that the fact that plants and bacteria have some properties in common is sufficient basis for holding that bacteria are to be excluded from patent coverage. * * *

* * * I do not find it improper to claim living organisms * * * .

In view of the discussed cases, the since 35 U.S.C. 101 does not expressly exclude patents to

living organisms, it is my opinion that living organisms, as claimed, may be patented if such claims also fulfill the other requirements of the statute.

He also expressed disagreement with the examiner's view that claim 5 defined a "product of nature," or that being a product of nature was sufficient reason, alone, for holding an invention nonstatutory. He made these observations:

Rather, I view that a "product of nature" as being something that "exists" in nature and therefore evidence that it may not be "new" as this expression finds meaning in the Patent Statute. Accordingly, I would treat "products of nature" like any other material and determine whether they are new or obvious in view of the state of the art.

Certainly vitamin B-12, as it exists in liver, and adrenalin, as it appears in adrenal glands, are products of nature, yet the courts have held (*Merck & Co., B-12* and *Parke Davis and Co., adrenalin*)¹ that when such materials are extracted and concentrated in a purified form they are patentable. Accordingly, it is not sufficient to determine whether the pure culture claimed is a product of nature.

OPINION

Under the peculiar circumstances of this case, in which the board switched the supporting reasoning for the rejection of claim 5 as for nonstatutory subject matter without expressly making a new rejection, we deem it prudent to clarify the issue we have to decide. The brief of the PTO Solicitor sees but a single issue:

¹*Merck & Co. v. Chase Chemical Co.*, 273 F. Supp. 68, 155 USPQ 139 (D. N.J. 1967); *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 116 USPQ 484 (CA 4 1958); *Parke Davis & Co. v. H. K. Mulford Co.*, 189 Fed. 95 (S.D. N.Y. 1911), *aff'd*, 196 Fed. 496 (CA 2 1912).

"whether *living* organisms are the kind of 'manufacture' or 'composition of matter' intended by Congress to be included within 35 U.S.C. 101." (Emphasis ours.) Appellants argue that issue, making no objection to the board having raised it *sua sponte*, and also—perhaps out of an abundance of caution—argue the product-of-nature question side-tracked by the board. Appellants forcefully presented the latter issue before the board and submitted affidavits of three experts in the field to the effect that the "biologically pure culture" of claim 5 is not found in nature. The evidence appears to us to be incontrovertible. The dissenting member of the board accepted it. The board did not refute it, and the solicitor has not challenged it. The circumstances persuade us that the board went in search of another reason to support the rejection because it realized the examiner's position was untenable. We consider the product-of-nature issue to have been abandoned and no longer in the case. However, since the solicitor indicated at oral argument that he was not sure the board had removed it entirely, we state that we find it wholly lacking in merit. The biologically pure culture of claim 5 clearly does not exist in, is not found in, and is not a product of, "nature." It is man-made and can be produced only under carefully controlled laboratory conditions.

We take note of the fact that, since their appearance before the board, appellants have added another statutory category string to their bow. Before the board, they argued that the claim 5 pure culture is a "manufacture" under §101. Before us they also argue that it is a "composition of matter," which is another §101 category. This is not a matter of great moment since there is considerable overlap between these two broad categories, notwithstanding what some textwriters have said. The arguments have not made a distinction between the two. If it is either, it is statutory subject matter, and it is not intellectually profitable to attempt a distinction in this regard.

We therefore proceed to a decision solely on the basis of the issue as the solicitor has stated it, deeming it to involve the single question of whether the uncontroverted fact that the biologically pure culture, *as claimed*, is *alive* removes it from the categories of inventions enumerated in §101. Our conclusion is that it does not.

As to what the issue is, however, we make one further clarifying observation. We do so in part because of the solicitor's statement that a similar issue was present but not decided in *In re Merat*, 519 F.2d 1390, 186 USPQ 471 (CCPA 1975), a case involving chicken breeding, and in part because of the board's reasoning herein. The solicitor's statement about *Merat* is correct, but we emphasize that we are not here deciding the issue left open in *Merat* or anything other than the issue before us in this case, whether the subject matter of claim 5 is within either of the terms "manufacture" or "composition of matter" in §101. In other words, we are not deciding whether living things in general, or, at most, whether any living things other than microorganisms, are within §101. These questions must be decided on a case-by-case basis and anything said herein is to be taken as said in the context of a discussion of the subject matter of claim 5 and §101.

As presented to us, the question is clearly one of first impression. There is a substantial volume of literature bearing on it, both directly and indirectly, which the solicitor has helpfully collected in his brief, containing some private views on the question on which, it seems to be agreed, no court has passed.

One of the peripheral court comments, the first to be cited, is from our opinion in *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974). All that the case has been cited for is a bit of dictum bearing on a hypothetical situation which was not before us. The case involved claims to a *process* of producing a particular known antibiotic by aerobically cultivating a particular strain of *Streptomyces bifurcus*. The claims were rejected for

obviousness under 35 USC 103 on references showing various strains of other *Streptomyces* species used for the same purpose. We reversed, holding that *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973), was controlling and that the new *Streptomyces bifurcus* strain *discovered by Mancy* himself as part of the invention being claimed could not be used as prior art in determining the obviousness under §103 of his claims to a process of using it to produce the old antibiotic. In comparing the facts of the case before us in *Mancy* with the facts of *Kuehl*, we said (499 F.2d at 1294, 182 USPQ at 306):

We recognize the differences between this case and the situation in *Kuehl*, where the novel zeolite used as a catalyst in the claimed hydrocarbon cracking processes was itself the subject of allowed claims in the application. Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we assume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a "product of nature." However, it is not required for unobviousness of the method-of-use claims that the new starting material be patentable * * * .

If it is not clear from the context that we were not discussing what is or is not statutory subject matter within §101 but only a difference between two cases which we found not to be a reason for distinguishing them, and that we were not expressing any view, even by way of dictum, on the patentability of living organisms as such, we now make it explicit that the thought underlying our presumption that Mancy could not have obtained a claim to the strain of microorganism he had described was simply that it *lacked novelty*. We were thinking of something pre-existing and merely plucked from the earth and claimed as such,

a far cry from a biologically pure culture produced by great labor in a laboratory and so claimed. The dissenting board member was entirely correct in so interpreting our *Mancy* dictum. The examiner relied on it only to support his product-of-nature reasoning, and the board majority did not mention it, having abandoned that reasoning. Furthermore, it now appears to us, in light of what we have learned in this case about the separation and identification of new strains of *Streptomyces*, that our dictum was ill-considered. Had we known what we now know, we would likely have abjured the stated presumption.

Guaranty Trust Co. v. Union Solvents Corp., supra, was cited by the examiner as "especially pertinent" and again by the solicitor as a "judicial precedent" solely for the following passage appearing at the very end of the long trial court opinion (54 F.2d at 410, 12 USPQ at 57, emphasis ours):

Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the *life process* of a living organism. *Were the patent for bacteria per se, a different situation would be presented.* As before stated, the patent is not for bacteria *per se*. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set forth in the specification and claims. *Undoubtedly there is patentable subject-matter in the invention.* *Cochrane v. Deener*, 94 U.S. 780, 24 L.Ed. 139; *Risdon Iron & Locomotive Works v. Medart*, 158 U.S. 68, 15 S.Ct. 745, 39 L. Ed. 899; *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453 (C.C.A. 2); *Dick v. Lederle Antitoxin Laboratories (D.C.)* 43 F.(2d) 628. [6 USPQ 40 (S.D. N.Y. 1930)].

The statement the examiner relied on, "Were the patent for bacteria *per se*, a different situation would be presented," is a trite observation of minimal magnitude as precedent, dealing with a non-issue on which no opinion was expressed. What we find of interest and,

indeed, "pertinent" is the fact that the defendant urged the unpatentability of claims because they involved a *life process* of a *living organism* and the court *rejected* the argument. At the outset, the opinion states that one of the defenses was "non-patentable subject matter." The real plaintiff in the case was Commercial Solvents Corporation, exclusive licensee under the Weizmann patent in suit, which corporation was making butyl alcohol and acetone by the Weizmann bacteriological fermentation process, and, with its predecessors, had been doing so since 1918. In 1929 the production was 107,500,000 pounds. The trial court noted that "The record shows that an important and extensive new industry has now been developed and established upon the Weizmann process." It was very clear to the court that it was dealing with a life process for, in describing the invention, it said, "'Fermentation' is the chemical change, or the decomposition into new chemical compounds, of a substratum, by living organisms, such, for example, as yeast or bacteria." On the issue whether a process dependent upon living organisms and their life processes was patentable subject matter, the court had no doubts. In the last case cited in the above quotation, *Dick v. Lederle*, two years earlier the court had found a scarlet fever toxin and antitoxin and process of making the same to be patentable subject matter notwithstanding the employment of life processes in their preparation. On appeal in the *Guaranty Trust* case, the Third Circuit Court of Appeals affirmed per curiam on the opinion of the trial judge, commenting, inter alia, that it had been persuaded "that the invention disclosed in the patent created a new and important commercial enterprise * * *."

These decisions illustrate what we believe to have been the state of the law ever since, namely, that *processes*, one of the categories of patentable subject matter specified in §101, are uniformly and consistently considered to be statutory subject matter notwithstanding the employment therein of living or-

ganisms and their life processes. Witness the action of the PTO in the present case in allowing the process claims. Other examples of such patentable process claims involving living bacteria are to be seen in the bacterial sewage treatment cases of which one is *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 21 USPQ 69 (CA 7 1934). (See quoted claims 8 and 10 of reissue patent No. 15,140 in fn. 4.) A still earlier one is the *Cameron Septic Tank Co.* case cited in *Guaranty Trust* and decided by the Second Circuit Court of Appeals in 1908, wherein the trial court was reversed and bacterial-action process claims were held valid and infringed. (The original "septic tank.") It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not effect their status under §101. Of course it is clear, as the dissenting board member noted, that there is nothing in the words of §101 which excludes patents for living organisms.

We cannot agree with the board majority's view that §101 "must be strictly construed." But even a "strict construction," whatever that may entail, fails to lead inexorably to the exclusion of a manufacture or composition of matter because it is alive. The statute makes no distinction between manufactures and compositions on the one hand and processes on the other. If the board is right in excluding products because there is life in them, then logic dictates that it should take the same position with regard to processes. But it does not do so. Indeed, in light of what the courts have done over the past seventy years in holding such process claims valid, it could not properly do so. We have never heard of a case holding that the categories of patentable subject matter, as enumerated in §101 or any of its predecessor statutes, should be strictly construed and the board has cited none.

In 1932, when the Board of Appeals was faced with an examiner's contention that a biological process for producing butyl and isopropyl alcohols by bacterial action was unpatentable because the bacteria were doing only what by nature they are capable of doing, its response was that *if such a view were accepted, it would hardly be possible to grant a patent on any chemical process*, indicating an early appreciation of the essential similarity of what we normally think of as "chemical reactions" and the complex *chemical* procedures wrought by the *life* processes of microorganisms. *Ex parte Prescott*, 19 USPQ 178 (1932). As a result of that decision, according to the report of the case, patent No. 1,933,683 was issued Nov. 7, 1933, for "Production of Butyl and Isopropyl Alcohols" with process claims. The board said (19 USPQ at 180):

We are unable to agree with the Examiner that processes involving bacterial action do not involve patentable subject matter * * * .

What we have before us is an industrial product used in an industrial process—a useful or technological art if there ever was one. See *In re Waldbaum*, 59 CCPA 940, 457, F.2d 997, 173 USPQ 430 (1972). The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses. According to an article cited but not relied on by the solicitor entitled "Microbiological Applications and Patents" by Harvey W. Edelblute in *The Encyclopedia of Patent Practice and Invention Management* at 567, edited by R. Calvert (1964), microbiological processes have long been used "to make beer, wine, cheese, bread, pickles and sauerkraut, rett flax, age tobacco, bate leather, produce silage and digest sewage." But more to the point here, in recent years, according to

Edelblute, they have come to be used to "produce a vast variety of chemicals and drugs such as alcohols, ketones, fatty acids, amino acids, vitamins, antibiotics, steroids, and enzymes." Edelblute provides a "far from complete list" of chemical reactions carried out by microorganisms, which he names, which include oxidation, reduction, condensation, esterification, amination, deamination, phosphorylation, hydrolysis, decarboxylation, methylation, dismutation, acylation, and dehydration.² In short, microorganisms have come to be important tools in the chemical industry, especially the pharmaceutical branch thereof, and when a new and useful tangible industrial tool is invented which is unobvious, so that it complies with the prerequisites to patentability other than the enumerated statutory categories, we do not see any reason to deprive it or its creator or owner of the protection and advantages of the patent system by excluding it from the §101 categories of patentable invention on the sole ground that it is alive. It is because it is alive that it is useful. The law unhesitatingly grants patent protection to new, useful, and unobvious chemical compounds and compositions, in which category are to be found the *products* of microbiological processes, for example, vitamin B-12 and adrenalin, referred to in note 1 above, and countless other pharmaceuticals. We see no sound reason to refuse patent protection to the microorganisms themselves—a kind of tool used by chemists and chemical manufacturers in much the same way as they use chemical elements, compounds, and compositions which are not considered to be alive, notwithstanding their capacities to react and to promote reaction to produce new compounds and compositions by chemical processes in much the same way as do microorganisms. We think it is in the public interest to include microorganisms within the terms "manufacture" and "composition of

²"Bacteria are universal biochemists * * *." A. Bryan, C. A. Bryan, & C. G. Bryan, *Bacteriology* v (6th ed. 1962).

matter" in §101. In short, we think the fact that microorganisms, as distinguished from chemical compounds, are alive as a distinction without legal significance and that disposes of the board's ground of rejection and the sole reason for refusal of a patent argued by the solicitor.

As for the board's fears that our holding will of necessity, or "logically," make all new, useful, and unobvious species of plants, animals, and insects created by man patentable, we think the fear is far-fetched. In any case, that question is not before us, as we have indicated above. Nor are we influenced by the legislative history of the Plant Patent Act of 1930 in the course of which nobody had anything to say about patent protection for microorganisms, so far as we know. The collective mind of Congress was not turned in that direction. We are not here concerned with interpretation of the Plant Patent Act as this court was in *In re Arzberger*, supra, which simply held that *that act* did not encompass bacteria.

The decision of the board affirming the rejection of claim 5 is *reversed*.

REVERSED

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Patent Appeal No. 76-712

IN THE MATTER OF THE APPLICATION
OF

MALCOLM E. BERGY, JOHN H. COATS,
AND VEDPAL S. MALIK

Serial No. 477,766

KASHIWA, Judge,* concurring.

I agree with the result and the reasoning of the opinion by Judge Rich joined by Chief Judge Markey. Nevertheless, I wish to emphasize, out of a superabundance of caution, that I read the majority opinion as setting forth an extremely limited holding. While the PTO and the dissenting opinion raise the specter of patenting higher forms of living organisms, quite clearly the majority opinion does not support such a broad proposition. Each case must necessarily be considered on its own facts. On the facts of this case, I join the narrow confines of the majority opinion.

*Judge of the United States Court of Claims sitting by designation pursuant to 28 USC 293 (a).

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Patent Appeal No. 76-712

IN THE MATTER OF THE APPLICATION
OF

MALCOLM E. BERGY, JOHN H. COATS,
AND VEDPAL S. MALIK

Serial No. 477,766

MILLER, Judge, dissenting, with whom BALDWIN, J., joins.

I do not agree that a biologically pure culture of microorganisms is within the scope of 35 USC 101 intended by Congress.

The board majority concluded—

[35 USC 101] does not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturalists and agriculturalists (35 U.S.C., Chapter 15, Sections 161-164). *If 35 U.S.C. 101 were to be broadly construed there would clearly not have been any necessity for Chapter 15 of 35 U.S.C.*

We are especially impressed by the legislative history of R.S. 4886 (U.S.C. Title 35, Section 31), the predecessor of the present Chapter 15 of 35 U.S.C.

We believe that the legislative history reveals a clear congressional intent that plants were not covered by the predecessor of 35 U.S.C. 101.

...
Based upon the legislative history . . . we do not believe that the terms "manufacture" or "composition of matter," as employed in 35 U.S.C. 101, were intended to encompass any living organism, whether plants or the microorganism appellants are claiming here. [Emphasis added.]

The response of the majority opinion here is simply:

Nor are we influenced by the legislative history of the Plant Patent Act of 1930 [ch. 312, 46 Stat. 376] in the course of which nobody had anything to say about patent protection for microorganisms. . . .

It then attempts to distinguish between microorganisms and more-complex living things, such as those included within the common means of "plants," saying:

The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses.

Such a distinction is purely gratuitous and clearly erroneous. The nature of organisms, whether microorganisms, plants, or other living things, is fundamentally different from that of inanimate chemical compositions. For example, both the microorganisms claimed herein and honeybees are alive, reproduce, and act upon other materials to form technologically useful products (lincomycin and honey, respectively). This cannot be said of chemical compositions. The weakness of the majority's position is further apparent from its failure to advance any rationale for distinguishing between different types of living things—particularly between a biologically pure culture of a microorganism and plants—for purposes of 35 USC 101.

I agree with the board majority that 35 USC 161, *et seq.*, whose original precursor was the Plant Protection Act of 1930 (1930 Act), and the legislative history of the 1930 Act support the conclusion that living organisms (*e.g.*, plants and biologically pure cultures of microorganisms) were not intended by Congress to be within the scope of 35 USC 101.

That Congress believed it necessary to enact a statute *extending* patent protection to certain plants (see *In re LeGrice*, 49 CCPA 1124, 1139, 301 F. 2d 929, 939,

133 USPQ 365, 374 (1962)) and to continue this protection in a *separate* provision of the present law demonstrates that Congress never intended that plants or other organisms be within the scope of the terms "manufacture" and "composition of matter." If, indeed, organisms were within the scope of such terms, the 1930 Act would have been superfluous. Presumably the 1930 Act was not superfluous, and the majority opinion here contains nothing to rebut that presumption. See *Platt v. Union Pacific Railroad*, 99 U.S. 48, 58 (1878); *In re Finch*, 535 F.2d 70, 71, 190 USPQ 64, 65, (CCPA 1976); *Skovgaard v. The M/V Tungus*, 252 F.2d 14, 17 (CA 3 1957), *aff'd* 358 U.S. 588 (1959); *United States v. Korpan*, 237 F.2d 676, 680 (CA 7 1956), *rev'd on other grounds*, 354 U.S. 271 (1957); *United States v. C.J. Tower & Sons*, 44 CCPA 1, 5, C.A.D. 626 (1956).

Moreover, the Senate committee report accompanying the bill which became the Plant Patent Act of 1930 (S. Rep. No. 315, 71st Cong., 2d Sess. (1930)) stated:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry The bill will remove the existing discrimination between plant developers and industrial inventors. [*Id.* at 1.]

This underscores Congressional understanding that plants were not patentable subject matter under the law then in effect, since, if they were, agriculture would already have been afforded "the same opportunity to participate in the benefits of the patent system." See *Bobsee Corp., v. United States*, 411 F.2d 231, 237 n.18 (CA 5 1969).

If, prior to the 1930 Act, plants had been within the scope of the patent statutes, as the majority opinion apparently assumes, a plant patent would have had to comply fully with what is now 35 USC 112; but after the 1930 Act, a plant patent for certain plants need not do so (since a plant patent could not be declared invalid if its description "is made as complete as is reasonably

possible"—see section 2 of the Plant Protection Act of 1930, 46 Stat. 376). This would have constituted a repeal of the full-compliance requirement in the case of such plants without any Congressional discussion thereof. Repeal by implication is not favored statutory construction. *FTC v. A.P.W. Paper Co.*, 328 U.S. 193, 202, 69 USPQ 215, 219 (1946). The conclusion follows that, prior to the 1930 Act, plants were not within the scope of the patent statutes.

The Plant Variety Protection Act, 7 USC 2321 *et seq.*, although enacted long after the original use of the terms "manufacture" and "composition of matter" appearing in 35 USC 101, further supports the conclusion that Congress did not intend organisms to be included within the scope of such terms. Both the Senate Judiciary Committee report (S. Rep. No. 91-1246, 91st Cong., 2d Sess. 3 (1970)) and the House Committee on Agriculture report (H.R. Rep. No. 91-1605, 91st Cong. 2d Sess. 1 (1970)) accompanying the bill (S. 3070) which became the Plant Variety Protection Act stated:¹

Under patent law, protection is presently *limited* to those varieties of plants which reproduce asexually, that is, by such methods as grafting or budding. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is *not* available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans. [Emphasis added.]

Thus, the Patent Act of 1952 was considered to be limited to plants falling under 35 USC 161, and 35 USC 101 was not considered to cover any plants whatsoever.

¹The bill was also reported on by the Senate Committee on Agriculture and Forestry (S. Rep. No. 91-1138, 91st Cong., 2d Sess. (1970)), which included a letter from the Under Secretary of Agriculture stating that the proposed legislation would provide the "incentive for private enterprise to undertake the research and development required to produce novel varieties of sexually produced plants."

The majority, in holding that the biologically pure culture of a microorganism defined by claim 5 constitutes patentable subject matter, relies heavily on the fact that processes of *using* the microorganism constitute patentable subject matter, saying:

It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not affect their status under § 101.

However, this court has pointed out that claims directed to processes of using an algorithm to *operate* a system constitute patentable subject matter while claims directed to the algorithm *per se* (or to methods of *calculating* using the algorithm) do not. See *In re Waldbaum*, 559 F.2d 611, 616, 194 USPQ 465, 470 (Cust. Ct. & Pat. App. 1977) (*Waldbaum II*). Compare *In re Richman*, 563 F.2d 1027, 1028 (Cust. Ct. & Pat. App. 1977) with *In re Flook*, 559 F.2d 21 (Cust. Ct. & Pat. App. 1977). Similarly here, the fact that claims directed to a process of *using* microorganisms constitute patentable subject matter does not logically compel the conclusion that claims to biologically pure cultures of microorganisms are patentable.²

²The majority also says that the claimed culture "is an industrial product used in an industrial process—a useful or technological art if there ever was one. See *In re Waldbaum*, 59 CCPA 940, 457 F.2d 997, 173 USPQ 430 (1972) [*Waldbaum I*]." However, the question is not whether the claimed culture is in a technological art, but whether the claimed subject matter was intended by Congress to be within the scope of 35 USC 101. Cf. *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673 (1972). Further, it is to be noted that claims in the *Waldbaum* application were rejected by the PTO after this court's decision in *Waldbaum I*, *supra*, based on the Supreme Court's reasoning in *Benson*, which rejection was affirmed by this court in *Waldbaum II*, *supra*.

Moreover, by emphasizing the microorganism portion of a claim to the process of using the microorganism, the majority opinion is taking an approach rejected by this court in cases such as *In re Chatfield*, 545 F.2d 152, 158, 191 USPQ 730, 736 (CCPA 1976), *cert. denied*, 46 U.S.L.W. 3203 (October 4, 1977), and *In re Deutsch*, 553 F.2d 689, 691 n.3, 193 USPQ 645, 647 n.3 (Cust. Ct. & Pat. App. 1977), namely dissecting the claim and concentrating on one portion of the claim in determining the issue of patentable subject matter.

The majority opinion says "it is in the public interest to include microorganisms within the terms 'manufacture' and 'composition of matter' in § 101." Although such a statement might be of interest to an appropriate committee of Congress, it has no relevance to the court's responsibility for determining Congressional intent. As noted by Chief Judge Markey in his concurring opinion in *In re McKellin*, 529 F.2d 1324, 1333, 188 USPQ 428, 437 (Cust. Ct. & Pat. App. 1976):

[T]he patent law is statutory. Our representative form of government requires that the enactments of its Congress must always be, at the very least, the starting point. There being no common law of patents, we should take care to fill the Holmesian interstices of the statute with judge-made law only under the gravest and most impelling circumstances.

The majority opinion, after stating that "[w]e consider the product-of-nature issue . . . no longer in the case," then finds the issue "wholly lacking in merit." Since the culture defined in claim 5 is not a "manufacture" or a "composition of matter" and since we do not have the view of the board majority on the product-of-nature issue, I would not reach that issue on this appeal.

In view of the foregoing, the decision of the board should be affirmed.

APPENDIX D

PATENT APPEAL NO. 76-712

OPINION AND DECISION OF BOARD OF APPEALS,
JUNE 22, 1976

Before MILESTONE and BLECH, *Examiners-in-Chief*,
and KATZ, *Acting Examiner-in-Chief*.

BLECH, *Examiner-in-Chief*.

This is an appeal from the final rejection of claim 5. Claims 1-4, the only other claims in the case, stand allowed.

The appealed claim is:

5. A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

The claimed invention relates to a biologically pure culture of a specific microorganism. The microorganism is capable of producing the antibiotic lincomycin.

No references have been applied against the appealed claim, the sole rejection being under 35 U.S.C. 101 in that it is drawn to non-statutory subject matter. 35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

It is the Examiner's position that the appealed claim defining a microorganism does not fall under any of the categories listed in Section 101 of Code 35 and, consequently, no patent can be granted thereon.

We have extensively researched prior court decisions for guidance to the question of whether or not a microorganism, being a living thing, is or is not within the realm of statutory patentable subject matter, but, other than possible non-controlling dicta, have not found any case directly in point.

It is our view that 35 U.S.C. 101 must be strictly construed and, when so interpreted, precludes the patenting of a living organism. We reach this conclusion on the basis that only those categories of subject matter specifically enumerated in the statute are patentable and a living organism does not fall within the scope of any of the categories listed. An analogous result has been reached by the courts with respect to nonpatentability of mental processes, printed matter or methods of doing business none of which are also expressly excluded by the indicated section of the statute, but neither can they be said or have been held to be included thereby.

Further, and even more significantly, this section of the statute does not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturists and agriculturalists (35 U.S.C., Chapter 15, Sections 161-164). If 35 U.S.C. 101 were to be broadly construed there would clearly not have been any necessity for Chapter 15 of 35 U.S.C.

We are especially impressed by the legislative history of R. S. 4886 (U.S.C. Title 35, Section 31), the predecessor of the present Chapter 15 of 35 U.S.C. We believe that the legislative history reveals a clear Congressional intent that plants were not covered by the predecessor of 35 U.S.C. 101. We quote from the report of the Committee on Patents, found on page 1319, of *In*

re *Arzberger*, 27 CCPA 1315, 112 F.2d 834, 1940 C.D. 653, 521 O.G. 272, 46 USPQ 32:

"The bill will remove the existing discrimination between plant developers and industrial inventors."

and further

"No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the genius whose patience, foresight, and effort have given a valuable new variety of *fruit or other plant* to mankind."

Based upon the legislative history as discussed in *Arzberger*, *supra*, we do not believe that the terms "manufacture" or "composition of matter," as employed at 35 U.S.C. 101, were intended to encompass any living organisms, whether plants or the microorganism appellants are claiming here.

If we were to adopt a liberal interpretation of 35 U.S.C. 101 new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and cross-breeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. 161, such as tuber propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. 101. We do not believe that Congress intended 35 U.S.C. 101 to encompass any living organisms, whether they be plants or microorganisms.

Taking the position that living organisms are non-statutory subject matter under 35 U.S.C. 101 we do not reach and need not decide whether patenting of the claimed microorganism is precluded due to it being a "product of nature." The affidavits under Rule 132 present in the case are thus not germane to the issue

which we consider is presented to us by the facts of this case.

The decision of the Examiner is affirmed.

AFFIRMED

BOARD OF APPEALS

/s/G. K. Milestone
G. K. MILESTONE
Examiner-in-Chief

/s/Blech
Examiner-in-Chief

KATZ, Acting Examiner-in-Chief, dissenting:

The majority bases its opinion strictly on the viewpoint that the terms "composition" and "manufacture," as employed in 35 U.S.C. 101, were not intended to encompass living organisms.

I consider that the bacteria culture claimed falls either into the category of "composition" or "manufacture" if steps were necessary to treat the bacteria to obtain the defined culture.

Appellants and the Examiner have relied on the following cases:

Guaranty Trust Co. of New York v. Union Solvents Corp., 54 F.2d 400, 12 USPQ 47;
In re Mancy et al., 499 F.2d 1289, 182 USPQ 303;
Merck & Co., Inc. v. Chase Chemical Company et al., 273 F Supp. 68 (D. N.J. 1967), 155 USPQ 139;
Merck & Co., Inc. v. Olin Mathieson Chemical Corporation, 253 F.2d 156 (CA 4, 1958), 116 USPQ 484;
Kuehmsted v. Farbenfabriken of Elberfeld Co., 179 Fed. 91 (CA 7, 1910), cert. den. 220 US 662;
Parke-Davis & Co. v. H. K. Mulford Co., 189 Fed. 95 (C.C. S.D. N.Y. 1911), aff'd 196 Fed. 496 (CA 2, 1912);

Ex parte Yale et al., 119 USPQ 256;
Ex parte Hillyer et al., 102 USPQ 126;
Ex parte Parke et al., 64 USPQ 335;
In re Bergstrom et al., 427 F.2d 55, 166 USPQ 256;
In re Williams, 36 CCPA 756, 171 F.2d 319, 80 USPQ 150; and
Funk Brothers Seed Company v. Kalo Inoculant Company, 76 USPQ 280.

In my determination of the issues, I have considered not only those cases, but also:

In re Arzberger, 27 CCPA 1315, 1940 C.D. 653, 112 F.2d 834, 521 O.G. 272, 46 USPQ 32;
Ex parte Grayson, 51 USPQ 413 (PO Bd. of App., 1941);
Armstrong Seatag Corporation v. Smith's Island Oyster Co., 254 Fed. Rep. 821;
Armour Pharmaceutical Co. v. Richardson-Merrell, Inc., 396 F.2d 70, 158 USPQ 9;
Kalo Inoculant Company v. Funk Brothers Seed Company, 161 F.2d 981, 74 USPQ 1; and
In re Davis et al., 49 CCPA 1196, 305 F.2d 501, 134 USPQ 256.

The Wegner article has also been studied:

Wegner, "Patent Protection for Microorganisms," *International Review of Industrial Property and Copyright Law*, ICC, Vol. 5, No. 3 (1974), pages 285-291.

None of the cases deal directly with the question of whether microorganism cultures fall within the statutory category of what may properly be patented, although a number of cases touch on the subject and may give guidance.

The Examiner has stressed the *Guaranty Trust Co.*, *In re Mancy et al.*, and *Funk Brothers* cases.

In the penultimate paragraph of the Guaranty Trust Co. decision, the Court comments that

"were the patent for bacteria *per se* a different situation would be presented."

The patent referred to is drawn to the manufacture of acetone and butyl alcohol by a fermentation process employing a certain strain of bacteria. The Court's ruling, however, does not indicate what the holding would be if the bacteria, *per se*, were to be claimed.

In the Mancy et al. case, all claims on appeal were drawn to a process. However, the CCPA expressed the following dictum:

"Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record is, as we understand it, a 'product of nature'."

Both the Examiner and appellants appear to be under the impression that the CCPA is inferring that new strains are products of nature and, accordingly, non-statutory.

I do not so interpret the Court's statement. The CCPA appears to indicate that while there is no art showing the strain, the strain, in actuality, is not novel since it exists in nature. It would then follow that the discovery, or isolation, of such strain does not make it new. Accordingly, the claim would not be obtained because it was to known subject matter, rather than on the basis that the subject matter was non-statutory.

The District Court's ruling, as described in the Court of Appeals decision in the Kalo Inoculant Company case, indicates that the District Court believed that the patentee's work "could not be classified under any subject matter defined as patentable by the Congressional Act."

However, of major interest is that in the appellate decisions, both the Circuit Court of Appeals (Kalo Inoculant v. Funk Brothers) and the Supreme Court (Funk Brothers v. Kalo Inoculant) strongly imply that mixtures of organisms, *per se*, are proper subject matter for which patents may be granted.

The majority of the U.S. Supreme Court, in the Funk Brothers case, did not conclude that bacteria mixtures are improper patent subject matter, and thus did not close out the controversy. Instead, they based their decision on the determination of patentability of the mixtures and found the claims invalid for want of invention.

In the Funk Brothers case, patentee discovered that certain strains of bacteria could be mixed and used to inoculate a number of different types of nitrogen-fixing plants. Prior to this discovery, it was necessary to use a specific bacteria strain for each type of plant since mixtures of strains were unsuitable, the different strains inhibiting each other.

The Court held that the composite culture was new and useful, but still not patentable since no species of bacteria in the mix acquired a different use, the combination did not produce a new bacteria, or a change in the six species of bacteria, and no enlargement of the range of utility since each species had the same effect it always had and the bacteria performed in their normal way. It was the Court's opinion that the discovery of the non-inhibiting action of certain strains of bacteria was merely a discovery of a hitherto unknown, but existing phenomenon of nature, which may not be monopolized.

Mr. Justice Frankfurter, in his concurring opinion, agreed with the Circuit Court of Appeals, and stated:

"Insofar as the court below concluded that the packaging of a *particular mixture of compatible strains is an invention and as such patentable*, I agree, provided not only that a new and useful property results from their combination, but also

that the particular strains are identifiable and adequately identified." (Underlining added).

Justice Frankfurter concluded, however, that the patentee had not properly identified the strains and thus was not entitled to a patent.

Mr. Justice Burton and Mr. Justice Jackson, in dissenting, stated:

"When the patentee discovered the existence of certain strains of bacteria which, when combined with certain other strains of bacteria, would infect two or more leguminous plants without loss of their respective nitrogen-fixing efficiencies, and utilized this discovery by segregating some of these mutually non-inhibitive strains and combining such strains into composite inoculants, *we agree with MR. JUSTICE FRANKFURTHER that the combinations so produced satisfied the statutory requirements of invention or discovery . . .* These products were a prompt and substantial commercial success, filling a long-sought and important agricultural need." (underlining added)

The dissenting Justices took the position that the invention was properly defined and thus patentable. Of major interest, however, is that they made it clear that they considered the subject matter itself to be statutory.

The majority opinion in Funk Brothers specifically ruled on the patentability of the mixture of organisms when compared to what was known in the art and what was present in nature, and did not deal directly with whether the subject matter itself is statutory. However, it appears reasonable that the Court must have dealt with the same first hurdle we have before us. Is the bacteria culture itself statutory? The Court seems to have acted on the assumption that the subject matter of the controversy was, like any other subject matter, not to be evaluated for patentability in the ordinary manner. At the very least, the majority holding can be said to be neutral on the subject of whether strains of

bacteria fall within the statutory classes of patentable subject matter.

However, I am strongly influenced by the positive and definitive language in the concurring and dissenting opinions. Both opinions state that the combination of bacteria cultures satisfy the statutory requirements. Neither opinion conflicts with the majority opinion in this regard.

Appellants have brought to the Board's attention patents which claim a composition of matter comprising spores of a certain bacteria in a carrier. Note U.S. Patents 3,632,747, 3,642,982 and 3,651,215. Patent 3,642,982 specifically claims a composition of living bacteria in an inert carrier, which may be a culture medium (claim 2). Such patents are not precedent, but they are of interest.

It is true that the courts have decided that certain categories of subject matter (mental processes, printed matter, methods of doing business) do not fall within the boundaries of Section 101, and that it was found necessary to enact a separate statute to provide protection to those who developed or discovered new plant varieties. However, this does not logically lead to a conclusion that Section 101 was not intended to provide patent protection for living organisms.

Of the various acknowledged non-statutory categories, plants are most akin to the living organisms. Both materials are alive. However, that is where the similarity stops. As held in the *Arzberger* case, living organisms (bacteria) are not plants within the meaning of the plant statute. While bacteria may possess some of the characteristics of plants, the word "plant" is used in its popular sense and not in its scientific sense since the statute was designed for the benefit of agriculturists. Thus, the exclusion of plants from 35 U.S.C. does not necessarily apply to bacteria.

Further, I do not believe that the fact that plants and bacteria have some properties in common is sufficient basis for holding that bacteria are to be excluded from

patent coverage. Such line of reasoning would, for example, preclude the patenting of plant-derived cellulosic materials, merely on the basis that plants also contain cellulose.

Since I do not find it improper to claim living organisms, I would make no distinction between a single living organism, or such organism mixed with other organisms or with non-living materials, such as carriers or culture mediums.

In view of the discussed cases, and since 35 U.S.C. 101 does not expressly exclude patents to living organisms, it is my opinion that living organisms, as claimed, may be patented if such claims also fulfill the other requirements of the statute.

I would determine whether the claimed culture is new or unobvious, as required by the statute.

Appellants urge that claim 5 is not directed to a product of nature, but rather to a biologically pure culture obtained by the work of a microbiologist. It is their view that clearly patentable subject matter is defined. Three affidavits have been submitted by appellants and, the uncontested evidence is that the biologically pure culture of claim 5 is not found in nature, that the type of microbe (actinomycetes), to which the microorganisms belongs, makes up a portion of the microbes found in certain sample of earth, that the microorganism belongs, makes up a portion of the metabolic activities and that a biologically pure culture must be produced before a microorganism can be taxonomically characterized, and, further, that the impure culture will not give the desired fermentation product.

The majority decision does not find sufficient reason to decide whether patenting of the claimed microorganism is precluded due to it being a "product of nature." However, because the Examiner has, in part, based his rejection on this theory, and since I do not agree that the claim is properly rejected solely because

it is drawn to a living organism, I will go into this aspect.

The expression "product of nature" does not appear in Section 101 and, as such, a material should not be excluded on that basis alone, as being nonstatutory. Rather, I view a "product of nature" as being something that "exists" in nature and therefore evidence that it may not be "new" as this expression finds meaning in the Patent Statute. Accordingly, I would treat "products of nature" like any other material and determine whether they are new or obvious in view of the state of the art.

Certainly vitamin B-12, as it exists in liver, and adrenalin, as it appears in adrenal glands, are products of nature, yet the courts have held (Merck & Co., B-12 and Parke Davis and Co., adrenalin) that when such materials are extracted and concentrated in a purified form they are patentable. Accordingly, it is not sufficient to determine whether the pure culture claimed is a product of nature. For a proper evaluation from the patentability aspect, such culture must be examined and evaluated on the basis of whether it meets the novelty and/or unobviousness requirements set forth in the statute.

I am tempted to give my view on the patentability of the pure culture of the defined organism. However, this issue has not been raised in this case. Before deciding, it would be appropriate to have the benefit of appellants' and the Examiner's viewpoints. Therefore, I would remand for a fuller consideration of this aspect.

BOARD OF APPEALS

/s/ Murray Katz

MURRAY KATZ

Examiner-in-Chief

(Acting)

APPENDIX E

PATENT APPEAL NO. 76-712

LETTER OF EXAMINER, FEBRUARY 6, 1975

- ☒ This application has been examined.
- ☒ Responsive to communication filed 1/27/75.
- ☒ This action is *made final*.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS LETTER.

* * * * *

PART II

Summary of Action

- 1. ☒ Claims 1-5 are presented for examination.
- 2. ☒ Claims 1-4 are allowed.

* * * * *

- 4. ☒ Claim 5 is rejected.

* * * * *

Claim 5 is rejected under 35 USC 101 as nonstatutory subject matter. Claim 5 claims a product of nature (*Streptomyces vellosus* NRRL 8037). See *In re Mancy et al.* 182 USPQ 303 at page 306, second sentence before [4].

Claims 1-4 are allowable in view of the declaration filed January 27, 1975.

This action is made FINAL.

/s/ A. Louis Monacell
A. LOUIS MONACELL
Examiner
Group Art Unit 172

LETTER OF EXAMINER, MARCH 11, 1975

- ☒ THE PERIOD FOR RESPONSE IS EXTENDED TO RUN 4 MONTHS FROM THE DATE OF THE FINAL REJECTION. 855 O.G. 1109.
- ☒ Appellant's Brief is due in accordance with Rule 192(a).

Appellant's response to the final rejection, filed 2/20/75, has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

* * * * *

- 4. ☒ The affidavit, exhibit or request for reconsideration has been entered but does not overcome the rejection.

* * * * *

/s/ A. Louis Monacell
A. LOUIS MONACELL
Examiner
Group Art Unit 172

APPENDIX F

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Appeal No. 77-535

Serial No. 260,563

IN THE MATTER OF THE APPLICATION OF

ANANDA M. CHAKRABARTY

DECIDED: MARCH 2, 1978

RICH, Judge

This appeal by an applicant for a patent, assignor to General Electric Company, is from a decision by the United States Patent and Trademark Office (PTO) Board of Appeals (board) affirming the rejection of claims 7-9, 13, 15, 17, 21, and 24-26 of application serial No. 260,563, filed June 7, 1972, entitled "Microorganisms Having Multiple, Compatible Degradative Energy-Generating Plasmids and Preparation Thereof." We reverse.

The Invention

In view of the legal issue presented, it is unnecessary to describe in detail the subject matter of the appealed claims, which is described in complicated biological terminology and is of a highly technical nature involving

the modification of bacteria to solve man's practical needs. In this instance, the immediate need is the important one of controlling oil spills, as one example, by the degradation of complex hydrocarbons such as crude oil and "Bunker C" oil through the action of microorganisms. Microorganisms, that is to say bacteria, are modified for this purpose by what is sometimes referred to as "genetic engineering," a term appearing in appellant's specification. It is also disclosed therein that prior to appellant's invention microbial strains were known that can decompose individual components of crude oil, any given strain degrading only a particular component of the oil. For this reason biological control of oil spills had involved the use of a mixture of strains on the theory that the cumulative degradative actions would consume the oil and convert it into a cell mass which, in turn, serves as food for aquatic life. However, in the use of such a mixture there was ultimate survival of but a portion of the initial collection of bacterial strains with the result that the bulk of the oil spill remained unattacked for a longer period. Appellant's invention involves the creation of a new strain of bacteria by the incorporation in a *single* cell, by transmission thereof of a plurality of compatible "plasmids," of a capacity for simultaneously degrading several different components of crude oil with the result that degradation occurs more rapidly. To make this non-technical description somewhat more intelligible we quote from the specification but two of its many definitions:

Extrachromosomal element . . . a hereditary unit that is physically separate from the chromosome of the cell; the terms "extrachromosomal element" and "plasmid" are synonymous; when physically separated from the chromosome, some plasmids can be transmitted at high frequency to other cells, the transfer being without associated chromosomal transfer.

Degradative pathway . . . a sequence of enzymatic reactions (e.g., 5 to 10 enzymes are produced by

the microbe) converting the primary substrate [i.e., oil] to some simple common metabolite, a normal food substance for microorganisms.

This sketchy background, it is hoped, will give some idea of the nature of the invention at bar as defined in illustrative claim 7 which reads:

7. A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.
[¹]

The specification disclosure contains examples of bacterial strains with four hydrocarbon degradative pathways and the statement: "If there is an upper limit to the number of energy-generating plasmids that will be received and maintained in a single cell, this limit is yet to be reached."

The PTO, speaking through the examiner as well as the board, has not questioned that appellant has invented and adequately disclosed strains of bacteria, within the definitions of his rejected claims, which are new, useful, and unobvious.

Neither has any question been raised by the PTO about the inventions of the rejected claims being in the useful or technological arts so that their protection for a limited time by patent would be an implementation of the Constitutional purpose of promoting progress in the "useful arts." Art. I, sec. 8, clause 8.

The Rejection and the Board's Decision

The decision and opinion of the board are quite similar to its action and reasoning in the recent case of *In re*

¹ As a matter of general interest, the assignee of appellant's invention has been granted British patent 1,436,573 containing this and other claims to the bacterium.

Bergy, 563 F.2d 1031, 195 USPQ 344 (CCPA 1977), wherein we reversed the decision of the board (subsequent to its decision herein).

In the present case, the board first pointed out that the examiner had rejected the appealed claims only under 35 USC 101² "on the ground that they are not encompassed by the provisions" thereof, advancing two reasons therefor: (1) that the claimed microorganisms are "products of nature" and (2) that they are drawn to "live organisms." The board reversed the examiner on point (1), agreeing with appellant that the claimed bacteria are not naturally occurring. This decision was expressed in a single sentence and the rest of the board's opinion was devoted to a discussion of the legal effect of the fact that the claimed bacteria are alive.

The board first discussed a number of cases which it had considered and concluded that there is "no case dealing directly with the point here in issue," including, possibly as of first importance, the Supreme Court's opinion in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). (In *Bergy*, supra, the board also stated that it had "not found any case directly in point.") The board then pursued exactly the same line of reasoning it did in *Bergy*, in large part in the same words, to reach the same conclusion it expressed in *Bergy*, that § 101 "does not include living organisms." The board's opinion that § 101 does not include any living organism was expressed in the form of its belief that Congress did not so intend. As in *Bergy*, this view was deduced from the enactment of the Plant Patent Act of 1930, citing this court's opinion in *In re*

²35 USC 101 reads:

§101. *Inventions patentable*

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Arzberger, 27 CCPA 1315, 112 F.2d 834, 46 USPQ 32 (1940).³

Responsive to the initial opinion of the board, appellant filed an extensive petition for reconsideration pointing out that the examiner had first raised the "living organism" question in his Answer to appellant's brief on his appeal to the board, wherefore appellant had not had an opportunity to present argument directed to the significance of the passage of the Plant Patent Act as an indication of the intent of Congress with respect to all living things, and argued that there was good reason to pass a special act for plants, other than the fact that they are alive. That reason was that plants cannot be so described in a patent specification as to enable the reader to produce them, as was required of other inventions by R.S. 4888, the predecessor of 35 USC 112, first paragraph, for which reason special legislation relaxing that requirement in the case of plants was necessary. Thus, appellant argued, the passage of the Plant Patent Act is not to be taken as "an expression of *any* sort of Congressional intent with respect to the patentability of living organisms." The Board's opinion on the petition reiterated that it knew of "no case dealing with the point here in issue," stating, more specifically, that "microorganisms per se have not squarely been ruled either eligible or ineligible for product patent coverage in any reported court or Patent Office decision," and adhered to its original opinion and decision. Appeal to this court was thereupon filed.

³ Although *Bergy* reached this court and was decided before the instant appeal (*Chakrabarty*), the latter was the first to be decided by the board. The two cases were clearly pending in the board at the same time and were decided by entirely different 3-man panels. *Chakrabarty* was decided May 20, 1976, and *Bergy* June 22, 1976. *Bergy* appealed forthwith but *Chakrabarty* filed a petition for reconsideration which was decided October 19, 1976. *Bergy* was argued in this court on March 3, 1977, and *Chakrabarty* on December 5, 1977. Any common language found in the board's two opinions—and there is much—presumably originated in the *Chakrabarty* case.

OPINION

Appellant's reply brief succinctly sums up the issue before us in these words:

In the instant appeal, appellants [sic] are seeking protection for a *new bacterium*, admittedly alive, in which such changes have been effected as to produce in this bacterium *new capabilities*. The Board of Appeals has agreed that this organism is *not* a "product of nature." If it be accepted that all things in our world are either products of nature or things produced by man, then by the process of elimination the Board of Appeals has agreed with appellant's contention that this new bacterium is a thing produced by man, i.e., a manufacture. It should follow, therefore, that * * * appellant has *already* met the requirements of Section 101.

The PTO has advanced but a single reason to support its contention that this is not so, namely, that the new bacterium is *alive*. That is precisely the single issue we had to pass on in *Bergy*. The decision of the board herein was rendered and the main briefs of the parties hereto were filed before we handed down our *Bergy* decision. Thereafter we invited the parties to file briefs on the bearing of the *Bergy* decision on this case. Appellant opined that "the *Bergy* decision appears to be controlling precedent * * *." The PTO brief said *Bergy* "might be considered dispositive of the issue presented [herein] if that decision remains a viable precedent." It then pointed to the fact that in *Bergy* the claim was directed to a "biologically pure culture" and that we had made it clear in our *Bergy* opinion that we were not deciding anything other than the question whether that claimed invention was a manufacture or a composition of matter within § 101, adding that "the Commissioner is uncertain whether *Bergy* has any bearing at all" in view of the fact that no claim here involved is so limited.

We do not consider the differences between the claims here and the claim in *Bergy* to be of any significance on the issue before us. In both cases the claims are directed to microorganisms and in both the *only* asserted objection to their patentability is that the microorganisms are alive and, for that reason *alone*, not within the § 101 categories of inventions which may be patented. We dealt fully with that identical issue and with the identical PTO arguments in *Bergy*. Nothing in the facts of this case requires that we add anything to what we there said. *Bergy* is, in this court at least, a controlling precedent.

The decision of the board is *reversed*.

REVERSED

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Appeal No. 77-535

Serial No. 260,563

IN THE MATTER OF THE APPLICATION OF

ANANDA M. CHAKRABARTY

MARKEY, Chief Judge, concurring.

I join in full the well reasoned and cogently stated majority opinion of my Brother Rich. These few remarks are prompted, with all due respect, by the dissenting views expressed by my Brothers Baldwin and Miller.

The sole issue before us is whether a man-made invention, admittedly novel, useful, and unobvious, is unpatentable because, and only because, it is "alive" (in the sense that microorganisms are "alive").

There are but two sources for manufactures and compositions of matter. They are God (or "nature" if one prefers) and man.

As presented to us, the invention is admittedly a "manufacture" by man. It therefore falls squarely within the language of the statute. The Patent and Trademark Office desires to read into the statute the word "dead" before "manufacture" and before "composition."*

* If the oil degrading activity of the present invention were stopped, i.e., if the inventor had "killed" his invention, (and if the invention had some utility in its dead form) the Patent and Trademark Office reasoning would require allowance of appellant's application.

The statute is not ambiguous. No Congressional intent to limit patents to dead inventions lurks in the lacuna of the statute, and there is no grave or compelling circumstance requiring us to find it there.

The Plant Patent Act of 1930 has nothing to do with the case before us and is of no aid in a search for what the intent of Congress *would have been* were it confronted with the present invention. Moreover, it is not necessary that we assume plants to have been within the scope of the patent statutes prior to 1930. The legislative history of the Plant Protection Act of 1930 or of the Plant Variety Protection Act, referred to in dissent, does not establish that Congress thought it was overcoming an objection to plants as unpatentable solely because they were "alive."

If Congressional intent must be sought, I would look to its primary source—the words of the statute itself. The Constitution grants Congress the power to recognize the exclusive rights of inventors in their discoveries for a limited time to encourage progress in the useful arts. Acting under that grant, Congress has provided that a patent shall issue on a "manufacture" or a "composition," where, as here, the invention meets the criteria established in the statute. It would thus in this case defeat the fundamental purpose of the Constitution, and of the patent laws enacted thereunder, if we were to interpret the statute as though it included the word "dead."

Similarly, analogy to oranges unfairly and unjustly resurrects the "product of nature" issue, which all parties had thought was settled. That question is not before us.

As with Fulton's steamboat "folly" and Bell's telephone "toy," new technologies have historically encountered resistance. But if our patent laws are to achieve their objective, extra-legal efforts to restrict wholly new technologies to the technological parameters of the past must be eschewed. Administrative difficulties, in finding and training Patent and Trademark Office

examiners in new technologies, should not frustrate the constitutional and statutory intent of encouraging invention disclosures, whether those disclosures be in familiar arts or in areas of the forefront of science and technology.

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Appeal No. 77-535

Serial No. 260,563

IN THE MATTER OF THE APPLICATION OF

ANANDA M. CHAKRABARTY

BALDWIN, Judge, dissenting.

I find the majority's statement of the issue in this case to be ambiguous and I disagree with Chief Judge Markey's broad statement of the issue. As I see it, the issue is whether applicant's modification of a clearly unpatentable living organism is sufficient to render the resulting living organism statutory subject matter. The majority apparently bases its argument on the belief that the claimed organisms must fall into one of two categories—"products of nature" ("manufactures" of God or nature) or patentable subject matter ("manufactures" of man). The PTO admits that the modified organism does not fall into the product-of-nature category, because the organism is not naturally occurring.¹ Therefore, the majority believes the modified organism must fall into the statutory subject matter category.

¹ Contrary to Chief Judge Markey's statement, I find no admission by anyone that the present invention is a statutory "manufacture." "Manufacture" and "man-made" are not synonymous for patent purposes. *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 8 USPQ 131 (1930).

But the dichotomy underlying this syllogism is not the law.

The law, as propounded by the Supreme Court, defines *three* alternatives. Between true "products of nature" and statutory subject matter or "manufactures" lies an intermediate category of things sufficiently modified so as not to be products of nature, but not sufficiently modified so as to be statutory "manufactures." Therein are found the borax-impregnated oranges of *American Fruit*, note 1 *supra*, and, in my view, the organisms now before us.

The present case focuses on the degree and nature of modification necessary to convert an admittedly unpatentable living thing into statutory subject matter. The Supreme Court, in *American Fruit*, considered whether impregnating fresh fruit skins with borax to prevent molding changed the natural products into statutory subject matter. The Court stated that, in order to become statutory subject matter, the new article must possess "a new or distinctive form, quality, or property." 283 U.S. at 11, 8 USPQ at 133. There must be a "change in the name, appearance, or general character of the" natural product. 283 U.S. and 12, 8 USPQ at 133. It is not enough that the new article is better adapted to the use for which the natural product was already suited. 283 U.S. at 12, 8 USPQ at 133. I read *American Fruit* as saying that a modified natural product does not become statutory subject matter until its essential nature has been substantially altered. The issue in the present case becomes whether the modification effected by appellant altered the essential nature of the starting material.

Applying the *American Fruit* rule to the modification of living organisms and to the case before us, I believe that the essential nature of the unpatentable organism with which applicant started was its animateness or life. Appellant has not changed this essential nature; he has not created a new life. Rather, he has merely genetically grafted an extra plasmid on to the

organism and, thereby, made the organism better at cleaning up oil spills. While this improvement in oil digesting ability does exclude the new organism from classification as a mere product of nature, like the borax-impregnated orange which was a better commercial product because it had a longer shelf life, this improvement in the utility for which the unpatentable starting material was already suited does not change the essential nature of the starting material and does not make the modified thing statutory subject matter.²

²I agree with Judge Miller's thorough analysis of the legislative history.

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Appeal No. 77-535

Serial No. 260,563

IN THE MATTER OF THE APPLICATION OF
ANANDA M. CHAKRABARTY

MILLER, Judge, dissenting.

I do not agree that appellant's claimed microorganisms are within the scope of 35 USC 101, and I join in the statement of the board—

We do not believe that Congress intended 35 U.S.C. 101 to encompass living organisms whether they be plants, modified microorganisms (such as bacteria), or modified multicellular organisms (such as mammals).

In *In re LeGrice*, 49 CCPA 1124, 1139, 301 F.2d 929, 939, 133 USPQ 365, 374 (1962), this court recognized that, under the Act of May 23, 1930, Pub. L. No. 245, 46 Stat. 376—

The patent law, as shown by the Committee Reports, was *extended* to plant patents in order to stimulate interest in the breeding and commercial development of new and valuable plant species. [Emphasis added.]

Both the Senate and House committee reports to which the court referred (S. Rep. No. 315, 71st Cong., 2d

Sess. 1 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930)) stated:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry. The bill will remove the existing discrimination between plant developers and industrial inventors.

The House Report, *id.* at 2, added:

No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the genius whose patience, foresight, and effort have given a valuable new variety of fruit or other plant to mankind.

Thus, the legislative history clearly shows Congressional understanding that, under the patent law in effect prior to the Plant Patent Act of 1930, reward for service to the public in developing new varieties of plants had not been extended to inventors. See *Bobsee Corp. v. United States*, 411 F.2d 231, 237 n. 18 (CA 5 1969).¹

As pointed out in my dissenting opinion in *In re Bergy*, 563 F.2d 1031, 195 USPQ 344 (CCPA 1977), if, prior to the 1930 Act, living organisms had been within the scope of the terms "manufacture" and "composition of matter" (as the majority and concurring opinions must assume), the 1930 Act would have been superflu-

¹ Each of the above-cited committee reports, at page 3, quotes Thomas A. Edison that—

Nothing that Congress could do to help farming would be of greater value and permanence than to give to the plant breeder the same status as the mechanical and chemical inventors now have through the patent law.

ous. There is a basic presumption in statutory construction that Congress does not legislate unnecessarily. See *Platt v. Union Pacific Railroad*, 99 U.S. 48, 58 (1878); *In re Finch*, 535 F.2d 70, 71, 190 USPQ 64, 65 (CCPA 1976); *Skovgaard v. The M/V Tungus*, 252 F.2d 14, 17 (CA 3 1957), *aff'd* 358 U.S. 588 (1959); *United States v. Korpan*, 237 F.2d 676, 680 (CA 7 1956), *United States v. C.J. Tower & Sons*, 44 CCPA 1, 5, C.A.D. 626 (1956). Neither the majority nor the concurring opinion is able to point to anything to rebut that presumption. If, after nearly two hundred years, it is desired to interpret the basic patent statute, for the first time, to cover living matter, the presumption poses a formidable and yet unrebutted challenge. Although advancement of technology would naturally be of interest to an appropriate committee of Congress, it has no relevance to the court's responsibility for determining Congressional intent. As noted by Chief Judge Markey in his concurring opinion in *In re McKellin*, 529 F.2d 1324, 1333, 188 USPQ 428, 437 (CCPA 1976):

[T]he patent law is statutory. Our representative form of government requires that the enactments of its Congress must always be, at the very least, the starting point. There being no common law of patents, we should take care to fill the Holmesian interstices of the statute with judge-made law only under the gravest and most impelling circumstances.

As also pointed out in my dissenting opinion in *Bergy*, if, prior to the 1930 Act, plants had been within the scope of the patent statutes (as the majority and concurring opinions must assume), a plant patent would have had to comply fully with what is now 35 USC 112; but, under the 1930 Act, a plant patent for asexually reproduced plants need not do so (since such a patent could not be declared invalid if its description "is made as complete as is reasonably possible"—see section 2 of the 1930 Act). This would have constituted a repeal of

the full-compliance requirement in the case of such patents without any Congressional discussion thereof. Repeal by implication is not favored statutory construction. *F.T.C. v. A.P.W. Paper Co.*, 328 U.S. 193, 202, 69 USPQ 215, 219 (1946). The conclusion follows that, prior to the 1930 Act, plants were not within the scope of the patent statutes.

As further pointed out in my dissenting opinion in *Bergy*, coverage of plants under the Patent Act of 1952 was considered by Congress to be limited to plants falling under Chapter 15 of 35 USC, and 35 USC 101 was not considered to extend to any plants whatsoever, thus making it necessary to enact the Plant Variety Protection Act (1970), 7 USC 2321 *et seq.*

Finally, the board made the following point:

We realize that 35 U.S.C. 101 does not expressly exclude patents on living organisms, but neither does it expressly exclude patents on mental processes, printed matter or methods of doing business.

This point was fully developed in my dissenting opinion in *Bergy*, where it was observed that claims directed to a process of using an algorithm to operate a system have been held to constitute patentable subject matter, while claims directed to the algorithm *per se* (or to methods of calculating, using the algorithm) do not.

Other points made by the majority in its opinion in *Bergy*, to which it refers here, are fully answered by my dissenting opinion in that case.²

The decision of the board should be affirmed.

²I am also persuaded by the point so well made in Judge Baldwin's dissenting opinion.

APPENDIX G

Opinion and Decision of Board of Appeals,

May 20, 1976

Before Magil and Schneider, Examiners-in-Chief, and Schain, Acting Examiner-in-Chief.

Schain, Acting Examiner-in-Chief.

This is an appeal from the final rejection of claims 7 through 9, 13, 15, 17, 21 and 24 through 26. Claims 27 through 32, 35 and 36, the only remaining claims in the case, have been allowed.

Claim 7 is illustrative of the appealed claims and reads as follows:

7. A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

No references have been applied against the appealed claims.

Claims 7 through 9, 13, 15, 17, 21 and 24 through 26 have been rejected under 35 U.S.C. 101 on the ground that they are not drawn to subject matter that is encompassed by the provisions of 35 U.S.C. 101. The examiner advances two reasons for this rejection of the claims on appeal:

1) They are "products of nature" and, hence, unpatentable.

2) They are drawn to live organisms and, hence, do not fit any of the categories of patentable subject matter as defined by 35 U.S.C. 101.

Appellant urges that the claimed bacterium does not exist in nature since it was appellant herself who produced a bacterium containing at least two distinct, stable, energy-generating plasmids. Appellant also main-

tains that there is nothing inherently unpatentable about living microorganisms, citing the Supreme Court's decision in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 US 127, 68 S. Ct. 440, 1948 CD 671, 608 OG 641, 76 USPQ 280.

In our determination of the issues, we have considered not only the Funk Brother's case, but also *In re Arzberger*, 27 CCPA 1315, 112 F.2d 834, 1940 CD 653, 521 OG 272, 46 USPQ 32, *Merck & Co., Inc. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 116 USPQ 484 (1958), *In re Mancy et al.*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974) and *Ex parte Grayson*, 51 USPQ 413 (PO Bd. App. 1941), all of the above cases having been cited either by the appellant or the examiner. In addition, we have considered the following decisions which we encountered in the course of our legal research: *Armstrong Seetag Corp. v. Smith's Island Oyster Co.*, 254 Fed. 821 (CCA, 4th Cir., 1918); *Armour Pharmaceutical Co. v. Richardson-Merrell, Inc.*, 396 F.2d 70, 158 USPQ 9 (CA 3, 1968); *Guaranty Trust Company of New York v. Union Solvent Corp.*, 54 F.2d 400, 12 USPQ 47 (DC Del., 1931); *Kalo Inoculant Company v. Funk Brothers Seed Company*, 161 F.2d 981, 74 USPQ 1 (CCA 7, 1947); and *In re Davis and Murdock*, 49 CCPA 1196, 305 F.2d 501, 1962 CD 456, 783 OG 1244, 134 USPQ 256.

A review of the above decisions reveals no case dealing directly with the point here in issue, although the penultimate paragraph of the Guaranty Trust Co. decision comments "[w]here the patent for bacteria *per se*, a different situation would be presented," and the review of the District Judge's decision in the Court of Appeals decision in the Kalo Inoculant Co. case appears to indicate that the District Judge believed the patentee's work "could not be classified under any subject defined as patentable by the Congressional Act." In *Mancy et al*, *supra*, all claims on appeal were drawn to a process. However, at page 306 of 182 USPQ, the CCPA expressed the following dictum:

"Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature.' "

In the case before us, however, we are directly confronted with the question whether living organisms (appellant's modified bacterium) are patentable subject matter under 35 U.S.C. 101.

We realize that 35 U.S.C. 101 does not expressly exclude patents on living organisms, but neither does it expressly exclude patents on mental processes, printed matter or methods of doing business. Even more significantly, this section of the statute does not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturists and agriculturists (35 U.S.C., Chapter 15, Sections 161-164). Were appellant's broad view of 35 U.S.C. 101 correct, there would have been no necessity for Chapter 15 of 35 U.S.C. We are especially impressed by the legislative history of R.S. 4886 (U.S.C. Title 35, Section 31), the predecessor of the present Chapter 15 of the 35 U.S.C. We believe that the legislative history reveals a clear Congressional intent that plants were not covered by the predecessor of 35 U.S.C. 101. We quote from the report of the Committee on Patents, found on page 1319 of *In re Arzberger*, *supra*:

"The bill will remove the existing discrimination between plant developers and industrial inventors,"

and further

"No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the

genius whose patience, foresight, and effort have given a valuable new variety of *fruit or other plant* to mankind."

Based upon the legislative history as discussed in *Arzberger, supra*, we do not believe that the terms "manufacture" or "composition of matter," as employed in 35 U.S.C. 101 were intended to encompass any living organisms, whether plants or the bacteria appellant is claiming here.

If we were to adopt appellant's liberal interpretation of 35 U.S.C. 101, new species of bacteria would be patentable, new types of insects, such as honeybees, would be patentable and new varieties of animals produced by selective breeding and cross-breeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. 161, such as tuber propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. 101. Finally, if 35 U.S.C. 101 encompasses living organisms which have been modified by the physical incorporation of additional plasmids into the cellular structure why would not 35 U.S.C. 101 encompass living multicellular organisms (including human beings) which have been modified by the physical incorporation (as by artificial transplants) of additional organs such as the liver or heart? Such a modified animal would be patentable, according to appellant's understanding of 35 U.S.C. 101. We do not believe that Congress intended 35 U.S.C. 101 to encompass living organisms whether they be plants, modified microorganisms (such as bacteria) or modified multicellular organisms (such as mammals).

We do not agree with appellant that the Supreme Court in the *Funk Brothers* case, *supra*, "sets forth clear and distinct rules by which a determination may be made as to the patentability of claims to living bacteria." (Page 9 of appellant's brief) The Supreme Court basically determined that the patented claims "lacked

invention;" i.e., they were obvious over the state of the art. We quote from page 132 of 333 US:

"But once nature's secret of the non-inhibitive quality of certain strains of the species of *Rhizobium* was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention."

Clearly, the Court was employing the language of obviousness and if the Court had decided the case in 1976 the statutory basis for holding the patent invalid would have been 35 U.S.C. 103, the successor to the old "lack of invention" criterion. See also *Armour Pharmaceutical, supra*, where the Court of Appeals, 3rd Circuit, applying the rationale of the *Funk Brothers* case, held a patent invalid because the invention represented no more than the exercise of ordinary skill. Thus, we conclude that the Supreme Court in *Funk Brothers* did not consider or decide the issue presented here; i.e., the question of whether living microorganisms are patentable under 35 U.S.C. 101.

We agree with appellant that the claimed bacteria may not be considered as being "products of nature" simply because from the record we must conclude that *Pseudomonas* bacteria containing two or more different energy generating plasmids are not naturally occurring. However, we emphasize that a human being with a transplanted liver or heart is also not naturally occurring.

In accordance with the preceding analysis, we conclude that 35 U.S.C. 101 does not encompass living organisms, whether single cell or multicellular. Therefore, we will sustain the rejection of claims 7 through 9, 13, 15, 17, 21 and 24 through 26 as not directed to subject matter which may be patented under 35 U.S.C. 101.

The decision of the examiner is affirmed.

164a

AFFIRMED

H. MAGIL
Examiner-in-Chief

JOHN H. SCHNEIDER
Examiner-in-chief

HOWARD E. SCHAIN
Examiner-in-Chief

(Acting)

BOARD OF APPEALS

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APPENDIX H

Letter of Examiner, January 11, 1974

Paper No. ____

[x] This application has been examined.

[x] Responsive to communication filed 12-6-73.

[x] This action is *made final*.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE THREE MONTH(S) ____ DAYS FROM THE DATE OF THIS LETTER.

PART I

The following attachment(s) are part of this action:

- a. [] Notice of References Cited, Form PO-892.
- b. [] Notice of Informal Patent Drawing, PO-948.
- c. [] Notice of Informal Patent Application, Form PO-152.
- d. []

PART II

Summary of Action

- 1. [x] Claims 7-9, 13, 15, 17, 21, 24-32 & 34-36 are presented for examination.
- 2. [x] Claims 27-29 are allowed.
- 3. [x] Claims 34-36 would be allowable if amended as indicated.

4. ☒ Claims 7-9, 13, 15, 17, 21, 24-26, 30-32 & 34-36 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ Claims _____ are withdrawn from consideration.

8. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

9. ☐ Since it appears that a discussion with applicant's representative may result in agreements whereby the application may be placed in condition for allowance, the examiner will telephone the representative within about 2 weeks from the date of this letter.

10. ☐ Receipt is acknowledged of papers under 35 USC 119, which papers have been placed of record in the file.

11. ☐ Applicant's claim for priority based on an application filed in _____ on _____ is acknowledged. It is noted, however, that a certified copy as required by 35 USC 119 has not been received.

12. ☐ Other

Claims 7-9, 13, 15, 17, 21 and 24-26 are rejected under 35 USC 101 as nonstatutory. These claims are not within the classes of subject matter patentable under section 101. Applicant urges that the claims drawn to his bacteria are patentable because they differ in kind from naturally occurring bacteria. However it is considered that applicants *Pseudomonas* differ at best in degree rather than in kind from other *Pseudomonas*. In any case, it is considered that the instant *Pseudomonas* is drawn to a thing occurring in nature that is substantially unaltered and thus nonstatutory subject matter. In this connection attention is directed to *Ex parte Grayson* (51 USPQ 413) where it was held that a shrimp with its head and digestive tract removed

is a thing occurring in nature which is substantially unaltered and is not a manufacture.

Claims 30-32 are rejected under 35 USC 112 as too broad in the use of the term "bacteria" where applicant has shown only that the *Pseudomonas* are effective. In view of the unique and unpredictable behavior of genetic engineering processes, it would not appear that other microorganisms would work. Claims 27-29 are allowed. Claims 30-32 and 34-36 are free of the prior art. Claims 34-36 would be allowable if they did not depend from rejected claims

This action is made *FINAL*.

/s/Alvin E. Tanenholtz
ALVIN E. TANENHOLTZ
Examiner
Group Art Unit 172

APPENDIX I

OPINION AND DECISION OF BOARD OF
APPEALS, OCTOBER 19, 1976

Before Magil and Schneider, Examiners-in-Chief, and
Schain, Acting Examiner-in-Chief.

Schain, Acting Examiner-in-Chief.

ON REQUEST FOR RECONSIDERATION

This is a petition for reconsideration of our decision of May 20, 1976, wherein we affirmed the rejection of claims 7 to 9, 13, 15, 17, 21 and 24 to 26.

We have carefully considered the arguments advanced by appellant, including the excerpts from the legislative history of the Plant Patent Act, the Petition for a Writ of Certiorari in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 US 127, 68 S. Ct. 440, 76 USPQ 280, the excerpts from British patent law and the Irons and Sears article from *Annual Review of Microbiology* (1975), but we find nothing therein to convince us that our decision was in error. The thorough research evidenced by the Irons-Sears article confirms our own statement at page 3 of the Board decision:

"A review of the above decisions reveals no case dealing directly with the point here in issue, . . ."

At page 322 of the Irons-Sears article, they note that:

"In contrast, microorganisms per se have not squarely been ruled either eligible or ineligible for product patent coverage in any reported court or Patent Office decision."

We do not agree with appellant that our decision amounts to a new ground of rejection; on the contrary, the statutory basis for both the Examiner's rejection and our affirmance is 35 USC 101 as explained at the top of page 2 of our decision of May 20, 1976.

The petition is granted to the extent of reconsidering our decision but is denied with respect to making any changes therein.

DENIED

H. MAGIL
Examiner-in-Chief

JOHN H. SCHNEIDER
Examiner-in-Chief

HOWARD E. SCHAIN
Examiner-in-Chief, (Acting)

BOARD OF APPEALS

Cur

Supreme Court, U.S.
FILED

DEC 14 1979

APPENDIX

MICHAEL RODAK, JR., CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-136

LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS,

Petitioner

—v.—

MALCOLM E. BERGY, ET AL.

LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS,

Petitioner

—v.—

ANANDA M. CHAKRABARTY

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEALS

PETITION FOR A WRIT OF CERTIORARI FILED JULY 27, 1979
CERTIORARI GRANTED OCTOBER 29 1979

In the Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-136

LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS, *Petitioner*

—v.—

MALCOLM E. BERGY, ET AL.

LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS, *Petitioner*

—v.—

ANANDA M. CHAKRABARTY

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEALS

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BOARD OF APPEALS

Serial No. 477,766

Docket No. 76-712

Filed August 16, 1976

IN THE MATTER OF THE APPLICATION OF
MALCOLM E. BERGY, JOHN H. COATS and
VEDPAL S. MALIK

DOCKET ENTRIES

DATE	PROCEEDINGS AND ORDERS
COUNSEL FOR APPELLANT: Roman Saliwanchik	
COMMISSIONER OF PATENTS	
August 30, 1976	Stipulation Under Rule 4.2(c) Correction or Modification of the Record, filed, and approved.
September 7, 1976	Above material received.
November 1, 1976	PRINTED TRANSCRIPT OF RECORD, FILED.
December 27, 1976	BRIEF FOR APPELLANT, filed.
February 8, 1977	Motion of Commissioner to extend time for filing brief to February 14, 1977, filed.
February 9, 1977	Above motion granted.
February 14, 1977	BRIEF FOR THE COMMISSIONER OF PATENTS AND TRADEMARKS, FILED.
February 16, 1977	Motion of appellants for an additional ten minutes for oral argument, filed.
February 18, 1977	Above motion granted.
March 3, 1977	Argued
October 6, 1977	Reversed, Rich, Judge. Concurring opinion by Judge Kashiwa. Dissenting opinion by Judge Miller with whom Judge Baldwin joins.

DATE PROCEEDINGS AND ORDERS

October 27, 1977 PETITION FOR REHEARING BY COMMISSIONER, filed.

November 4, 1977 OPPOSITION TO PETITION FOR REHEARING BY APPELLANT, FILED.

November 23, 1977 Petition for rehearing denied. Judge Baldwin and Judge Miller would grant the petition.

November 30, 1977 FINAL MANDATE ISSUED TO THE COMMISSIONER OF PATENTS AND TRADEMARKS

February 14, 1978 Extension of time for Solicitor General to file certiorari in Supreme Court to April 22, 1978, granted by Justice Brennan.

April 20, 1978 Petition for Writ of Certiorari filed in Supreme Court of the United States, No. 77-1503.

July 26, 1978 Order of Supreme Court granting petition for writ of certiorari, vacating judgment, and remanding case for further consideration in light of *Parker v. Flook* (Appeal No. 77-512, decided 6/22/78).

August 8, 1978 Order restoring appeal to the calendar with supplementary briefs to be filed directed solely to the effect of *Parker v. Flook*; appellant's brief due on or before September 18; Commissioner's brief due on or before October 18; reply brief due on or before November 1. Case set for hearing November 6, 1978.

September 1, 1978 SUPPLEMENTAL BRIEF FOR APPELLANT, filed.

September 18, 1978 BRIEF FOR AMICUS CURIAE FOR UNIVERSITY OF CALIFORNIA, filed.

Sept. 18, 1978 Consent of appellant and Commissioner of Patents to University of Calif. filing brief Amicus Curiae, filed.

Sept. 18, 1978 Motion of American Patent Law Assn. for leave to file two typewritten Amicus Curiae briefs and extend time for filing requisite number of briefs to Sept. 22, 1978, filed.

DATE PROCEEDINGS AND ORDERS

September 20, 1978 Above motion of APLA, granted.

Sept. 21, 1978 Consent by Commissioner to APLA brief Amicus curiae, filed.

September 22, 1978 BRIEF FOR AMICUS CURIAE FOR AMERICAN PATENT LAW ASSN., filed.

October 17, 1978 SUPPLEMENTAL BRIEF FOR THE COMMISSIONER OF PATENTS AND TRADEMARKS, FILED.

November 6, 1978 Argued.

March 29, 1979 Reversed, Rich, J. Concurring opinion by Judge Baldwin. Dissenting opinion by Judge Miller.

April 20, 1979 FINAL MANDATE ISSUED TO THE COMMISSIONER OF PATENTS AND TRADEMARKS

June 15, 1979 Letter from Supreme Court re extension of time for Commissioner to file Writ of Certiorari to July 27, 1979 in jacket.

July 27, 1979 Petition for writ of certiorari filed in the Supreme Court of the United States; No. 79-136.

October 29, 1979 Petition for Writ of Certiorari, granted.

Patent Appeal No. 76-712

APPLICATION OF MALCOLM E. BERGY, JOHN H. COATS AND VEDPAL S. MALIK, FILED JUNE 10, 1974, SERIAL NUMBER 477,766, FOR PROCESS

ABSTRACT OF THE DISCLOSURE

Microbiological process for preparing the antibiotic lincomycin at temperatures ranging from 18° C. to 45° C. using the newly discovered microorganism *Streptomyces vellosus*. The subject process advantageously results in the preparation of lincomycin without the concomitant production of lincomycin B (4'-depropyl-4'-ethylincomycin). The absence of lincomycin B production results in increased lincomycin recovery efficiency.

BACKGROUND OF THE INVENTION

The antibiotic lincomycin, formerly known as lincolnensin, can be produced by the microorganism *S. lincolnensis* var. *lincolnensis*, NRRL 2936, as disclosed in U.S. Patent 3,086,912. The incubation temperature range disclosed in said patent for the production of lincomycin is 18° to 40° C., and preferably 26° to 30° C. Also produced during the lincomycin fermentation is the compound known as lincomycin B. Though lincomycin and lincomycin B have activity against essentially the same spectrum of microorganisms, it is known that lincomycin B is significantly less active against said microorganisms than is lincomycin. Accordingly, lincomycin is the preferred antibiotic of the two.

In conducting the above fermentation, it is necessary to use a large amount of cooling water in most fermentation equipment to maintain the desired fermentation temperature. Further, the maintenance of a temperature within the range of 18° C. to 40° C., though essential for antibiotic production as disclosed above, is conducive to the development and proliferation of contaminating microorganisms in the fermentation vessel.

BRIEF SUMMARY OF THE INVENTION

The subject invention concerns the fermentation preparation of lincomycin by the novel microorganism *Streptomyces vellosus* var. *vellosus*, NRRL 8037, at a temperature range of 18° to 45° C. It has been found, unexpectedly, that the titer of lincomycin produced at 45° C. is comparable to that which is produced at 28° C. The production of lincomycin at 28° C. and 45° C. for the microorganism of the subject invention is shown in the following table. The zone sizes of inhibition are given in millimeters. The test is a standard microbiological disc plate assay using 13 mm. paper discs.

Organism	28° C.	45° C.
<i>Bacillus subtilis</i>	21	18
<i>Staphylococcus aureus</i>	22	24
<i>Sarcina lutea</i>	31	29
<i>Klebsiella pneumoniae</i>	0	0
<i>Escherichia coli</i>	0	0
<i>Salmonella schottmuelleri</i>	0	0
<i>Mycobacterium avium</i>	22	25
<i>Penicillium oxalicum</i>	0	0

The results shown in the above table are unexpected since our tests have shown that *S. lincolnensis* var. *lincolnensis*, NRRL 2936, does not produce lincomycin when incubated at a temperature of about 45° C.

A distinct advantage in using this microorganism to prepare lincomycin is the need for less fermentor cooling capacity. The need for less cooling capacity is especially significant in high temperature climates and in areas having limited water supplies since water is the generally used means for cooling and maintaining fermentation temperatures. A further distinct advantage in the process of the subject invention is that lincomycin is produced without the concomitant production of lincomycin B.

DETAILED DESCRIPTION OF THE INVENTION

The Microorganism

The novel actinomycete used according to this invention for the production of lincomycin is *Streptomyces*

vellosus. One of its strain characteristics is the production of lincomycin without the concomitant production of lincomycin B. Another of its strain characteristics is the production of comparable titers of lincomycin at a temperature of 28° C. and 45° C. A subculture of this living organism can be obtained upon request from the permanent collection of the Northern Regional Research Laboratories, Agricultural Research Services, U.S. Department of Agriculture, Peoria, Illinois, U.S.A. Its accession number in this repository is NRRL 8037.

The microorganism of this invention was studied and characterized by Alma Dietz of the Upjohn Research Laboratory.

A thermotolerant *Streptomyces* species isolated from Arizona soil produces the antibiotic lincomycin. The culture is readily differentiated from other lincomycin-producers as may be noted in Table 4. The thermotolerant property, the microscopic characteristics of long, straight spore chains coiled at the tip, spores with long spines and hairs, and the distinctive antibiotic-producing capability of *Streptomyces vellosus* are not reported for any of the *Streptomyces* species with blue-gray spore color mass cited in the significant *Streptomyces* taxonomy publications of Hütter [Hütter, R. 1967. Systematik der Streptomyceten unter besondere Berücksichtigung der von ihnen gebildeten Antibiotica. S. Karger, Basel], Krassilnikov [Krassilnikov, N. A. et al. 1966. Biology of Antibiotic-Producing Actinomycetes, Akademiya Nauk SSSR. Edited by Ya. I. Rautenstein. Published for the U.S. Department of Agriculture and the National Science Foundation, Washington, D.C. by the Israel Program for Scientific Translations], Kutzner [Kutzner, H. J. 1956. Beitrag zur Systematik und Ökologie der Gattung *Streptomyces* Waksman et Henrici. Diss. Landw. Hochst. Hohenheim], Pridham, et al [Pridham, T. G., C. W. Hesseltine, and R. G. Benedict. 1958. A guide for the classification of streptomycetes according to selected groups. Placement of strains in morphological sections. Applied Microbiol. 6:52-79], Shirling and Gottlieb [Shirling, E. B., and D. Gottlieb. 1968. Cooperative description of type cultures of *Streptomyces*. II. Species descriptions from first study.

Int. J. of Syst. Bacteriol. 18:69-189; Shirling, E. B. and D. Gottlieb. 1968. Cooperative description of type cultures of *Streptomyces*. III. Additional species descriptions from first and second studies. Int. J. of Syst. Bacteriol. 18:279-392; Shirling, E. B. and D. Gottlieb. 1969. Cooperative description of type cultures of *Streptomyces*. IV. Species descriptions from the second, third and fourth studies. Int. J. of Syst. Bacteriol. 19:391-512; and Shirling, E. B. and D. Gottlieb. 1972. Cooperative description of type strains of *Streptomyces*. V. Additional descriptions. Int. J. of Syst. Bacteriol. 22:265-394], Trejo [Trejo, W. H. and R. E. Bennett. 1963. *Streptomyces* species comprising the blue-spore series. J. Bacteriol. 85:676-690], or Waksman [Waksman, S. A. 1961. The actinomycetes, vol. 2, Classification, identification, and descriptions of genera and species. The Williams & Wilkins Co., Baltimore]. Therefore, it is proposed that this isolate be designated *Streptomyces vellosus* Dietz, sp.n. and that this type species be designated the type variety *Streptomyces vellosus* var. *vellosus*. The species and variety designations are made in accordance with the Rules set forth in the International Code of Nomenclature of Bacteria [International Code of Nomenclature of Bacteria. 1966. Edited by the Editorial Board of the Judicial Commission of the International Committee on Nomenclature of Bacteria. Int. J. Syst. Bacteriol. 16:459-490].

Streptomyces vellosus Dietz, sp. n.

Color characteristics. Aerial growth blue-gray to gray. Melanin-positive. Color on Ektachrome [Dietz, A. 1954. Ektachrome transparencies as aids in actinomycete classification. Ann. N.Y. Acad. Sci. 60:152-154] is given in Table 1. Reference color characteristics are given in Table 2. *Streptomyces vellosus* may be placed in the Blue (B) and White (W) color series of Tresner and Backus [Tresner, H. D., and E. J. Backus. 1962. System of color wheels for Streptomycete taxonomy. Applied Microbiol. 11:335-338].

Microscopic characteristics. Spore chains long, straight with a tight to open coil at the tip. Spore chains spiral

(S) as defined by Pridham *et al.* [Pridham, T. G., C. W. Hesseltine, and R. G. Benedict. 1958. A guide for the classification of streptomycetes according to selected groups. Placement of strains in morphological sections. *Applied Microbiol.* 6:52-79]. Spores large, mostly oval. Spore surface adorned with long spines and hairs. Spore surface hairy as defined by Dietz and Mathews [Dietz, A. and J. Mathews. 1971. Classification of *Streptomyces* spore surfaces into five groups. *Appl. Microbiol.* 21:527-533].

Cultural and biochemical characteristics. See Table 3.

Carbon utilization. The growth of *S. vellosus* on carbon compounds was determined using the synthetic media of Pridham and Gottlieb [Pridham, T. G., and D. Gottlieb, 1948. The utilization of carbon compounds by some Actinomycetales as an aid for species determination. *J. Bacteriol.* 56:107-114] and of Shirling and Gottlieb [Shirling, E. B., and D. Gottlieb. 1966. Methods for characterization of *Streptomyces* species. *Int. J. of Syst. Bacteriol.* 16:313-330]. In the former, the culture showed trace growth on the control (basal medium without a carbon compound), dulcitol, *D*-sorbitol, sodium oxalate, and sodium tartrate, moderate growth on sodium acetate, sodium citrate, and sodium succinate; good growth on *D*-xylose, *L*-arabinose, rhamnose, *D*-fructose, *D*-galactose, *D*-glucose, *D*-mannose, maltose, sucrose, lactose, cellobiose, raffinose, dextrin, inulin, soluble starch, glycerol, *D*-mannitol, and inositol. The culture did not grow on salicin, phenol, cresol, sodium formate or sodium salicylate. In the medium of Shirling and Gottlieb the culture grew slightly on the negative control (basal medium without a carbon compound) as well on the positive control (basal medium with *D*-glucose). Growth was equal to or better than on the basal medium plus glucose on *D*-xylose, inositol, *D*-mannitol, rhamnose and raffinose. Growth was significantly better than on the negative control but less than on the *D*-glucose control on *L*-arabinose, sucrose, and *D*-fructose. Growth on cellulose was doubtful.

Temperature. *S. vellosus* is a thermophilic actinomycete. It grows well at temperatures of 18-55 C. Optimum growth occurs at 28-37 C. in 10-14 days; at 45 C. in 48 hours.

Antibiotic-producing properties. *S. vellosus* produces the antibiotic lincomycin.

Source. Soil from Arizona.

Type culture. *Streptomyces vellosus* Dietz, sp.n NRRL 8037.

Type variety. *Streptomyces vellosus* var. *vellosus* NRRL 8037.

TABLE 1

*Appearance of Streptomyces vellosus on Ektachrome**

Agar Media	Surface	Reverse
Bennett's	Gray	Tan-brown
Czapek's sucrose	Trace gray	Yellow-tan
Maltose tryptone	—	Brown
Peptone-iron	—	Brown
0.1% Tyrosine	Trace blue-gray	Brown
Casein-starch	Blue-gray	Tan-brown

* Dietz, A. 1954. Ektachrome transparencies as aids in actinomycete classification. *Ann. N.Y. Acad. Sci.* 60:152-154.

TABLE 2

Reference Color Characteristics of *Streptomyces vellosus*

Agar medium	Determination	Color Harmony Manual 3rd ed., 1948 •	NBS Circular 553, 1955 ••
Bennett's		(g)	
	S	15ba to 5ba blue tint to shell pink	184m very pale blue 189gm bluish white 9m pinkish white
	R P	3gc light tan 3ie camel, maple sugar, Tan	76gm light yellowish brown 76m light yellowish brown 77g moderate yellowish brown
Czapek's sucrose	S	3cb sand	—
	R	3ec bisque, light beige	79gm light grayish yellow- ish brown
	P	—	90 grayish yellow
Maltose-tryptone	S	5ba shell pink	9 pinkish white
	R	31g adobe brown, cinna- mon brown, light brown	77gm moderate yellowish brown
	P	3ie camel, maple sugar, tan	76m light yellowish brown 77g moderate yellowish brown

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TABLE 2 CON'T

Reference Color Characteristics of *Streptomyces vellosus*

Agar medium	Determination	Color Harmony Manual 3rd ed., 1948 •	NBS Circular 553, 1955 ••
Hickey-Tresner	S	15ba to 3cb blue tint to sand	184m very pale blue 189m bluish white
	R	31g adobe brown, cinna- mon brown, light brown	77m moderate yellowish brown
	P	31e cinnamon, yellow maple	76m light yellowish brown
Yeast-extract- malt extract (ISP-2)	S	15ba to 2ba blue tint to pearl, shell tint	184m very pale blue 189gm bluish white 92gm yellowish white
	R	3b	74g strong yellowish brown
	P	31e	76m light yellowish brown 74g strong yellowish brown 76m light yellowish brown
Oatmeal (ISP-3)	S	15cb cloud blue	184m very pale blue 190g light bluish gray 90 gm grayish yellow
	R	2gc bamboo, chamois	—
	P	—	—
Inorganic- salts starch (ISP-4)	S	19dc aqua gray	149g pale green 190m light bluish gray

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TABLE 2 CON'T

Reference Color Characteristics of *Streptomyces vellosus*

Agar medium	Determination	Color Harmony Manual 3rd ed., 1948 •	NBS Circular 553, 1955 ••
Glycerol- asparagine (ISP-5)	R	2fb bamboo, buff, straw, wheat	87g moderate yellow 89m pale yellow
	P	—	—
	S	15ba blue tint	184m very pale blue 189gm bluish white
	R	2fb bamboo, buff, straw, wheat	87g moderate yellow 89m pale yellow
	P	—	—

S = Surface (g) = all from glossy surface of color chip
g = glossy surface of color chip

R = Reverse m = matte surface of color chip

P = Pigment gm = glossy or matte surface of color chip

• Jacobson, E., W. C. Granville, and C. E. Foss. 1948. Color harmony manual, 3rd ed. Container Corporation of America, Chicago, Illinois.

•• Kelly, K. L., and D. B. Judd. 1955. The ISCC-NBS method of designating colors and a dictionary of color names. U.S. Dept. Comm. Circ. 553.

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TABLE 3

Cultural and Biochemical Characteristics of *Streptomyces vellosus*

Medium	Surface (aerial growth)	Reverse	Other Characteristics
<i>Agar media</i>			
Peptone-iron	None at 28 C. Gray at 45 C.	Brown	Brown pigment Melanin-positive
Calcium-malate	Trace white	Colorless	No pigment Malate not solubilized
Glucose- asparagine Skim milk	Pale pink-white	Cream at 28 C. Olive at 45 C.	Yellow pigment at 28 C. No pigment at 45 C.
	Trace gray at 28 C. None at 45 C.	Tan brown	Tan brown pigment Casein not solubilized
Tyrosine	Trace gray at 28 C. Fair gray at 45 C.	Brown at 28 C. Tan at 45 C.	Brown pigment at 28 C. Tan pigment at 45 C. Tyrosine not solubilized at 28 C.
			Tyrosine solubilized under growth at 45 C.
Xanthine	None at 28 C. Pink white at 45 C.	Yellow	Yellow pigment Xanthine not solubilized

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TABLE 3 CON'T
Cultural and Biochemical Characteristics of *Streptomyces vellosus*

Medium	Surface (aerial growth)	Reverse	Other Characteristics
Nutrient starch	None at 28 C. Pink-white at 45 C.	Yellow tan at 28 C. Yellow at 45 C.	Yellow tan pigment at 28 C. Yellow pigment at 45 C. Starch not hydrolyzed
Yeast extract- malt extract	Pink white (best at 45 C.)	Red tan at 28 C. Tan at 45 C.	Red tan pigment at 28 C. Tan pigment at 45 C.
Bennett's	Pale cottony blue-white	Tan	Tan pigment
Czapek's sucrose	Pale cream pink	Yellow	Yellow pigment
Maltose-tryptone	Pale cottony blue-white	Brown	Brown pigment
Hickey-Tresner	Pale cottony blue-white	Orange-tan	Pale tan pigment
Peptone-yeast extract-iron (ISP-6)	None	Brown	Brown pigment Melanin-positive
Tyrosine (ISP-7)	Pink-white	Brown	Brown pigment Melanin-positive

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TABLE 3 CON'T
Cultural and Biochemical Characteristics of *Streptomyces vellosus*

Medium	Surface (aerial growth)	Reverse	Other Characteristics
<i>Gelatin Media</i> Plain	—	—	Brown pigment at surface Olive pigment top half No liquefaction
Nutrient	—	—	Brown pigment at surface Tan pigment throughout No liquefaction—2 tubes Trace liquefaction—2 tubes
<i>Broth media</i> Synthetic nitrate	—	—	Colorless vegetative growth throughout broth and at base No pigment Nitrate not reduced to nitrite
Nutrient nitrate	—	—	Colorless compact bottom growth Yellow pigment Nitrate not reduced to nitrite
Litmus milk	White-gray aerial growth on surface ring	—	Brown pigment Litmus reduced pH 6.8

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TABLE 4

Comparison of *Streptomyces vellosus* with other lincomycin-producers

	<i>S. vellosus</i> NRRL 8037	<i>S. lincolnensis</i> NRRL 2936	<i>S. espinosus</i> NRRL 3890
Aerial mycelium	Blue-Gray to gray	Cream to pink to gray	Gray green
Melanin	Positive	Positive	Negative
Spore chains	Spiral (S)-very long and coiled at tip	Long flexuous (RF)	Short, straight to flexuous to open spiral (RF, RA)—short
Spores	Spherical	Rectangular	Spherical
Spore surface	Long spines and hairs	Smooth with surface detail	Thorny to spiny—transition to hairy on some spines
Calcium malate agar	Malate not solubilized	Malate not solubilized	Malate not solubilized
Skim milk agar	Casein not solubilized	Casein not solubilized	Casein solubilized
Tyrosine	Not solubilized	Solubilized	Solubilized
Xanthine	Not solubilized	Solubilized around growth	Not solubilized
Nutrient starch	Starch not hydrolyzed	Starch hydrolyzed	Starch hydrolyzed

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TABLE 4 CON'T

Comparison of *Streptomyces vellosus* with other lincomycin-producers

	<i>S. pseudogriseolus</i> <i>chemovar linmyceticus</i> NRRL 3985	<i>S. variabilis</i> <i>chemovar liniabilis</i> NRRL 5618
Aerial mycelium	Gray to white to red	Gray to white
Melanin	Negative	Negative
Spore chains	Short to moderately long straight (RF) to open spiral (RA) to spiral (S)	Short to moderately long flexuous (RF) to open spiral (RA)
Spores	Oval to oblong	Oval to oblong
Spore surface	Sparsely spiny to smooth	Smooth to poorly warty to spiny
Calcium malate agar	Malate not solubilized	Malate solubilized
Skim milk agar	Casein solubilized under growth	Casein solubilized
Tyrosine	Solubilized	Solubilized
Xanthine	Solubilized	Solubilized
Nutrient starch	Starch hydrolyzed	Starch hydrolyzed around growth

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Lincomycin is produced by the novel microorganism of the subject invention when said microorganism is grown in an aqueous nutrient medium under submerged aerobic conditions. It is to be understood also that for the preparation of limited amounts surface cultures and bottles can be employed. The organism is grown in a nutrient medium containing a carbon source, for example, an assimilable carbohydrate, and a nitrogen source, for example, an assimilable nitrogen compound or proteinaceous material. Preferred carbon sources include glucose, brown sugar, sucrose, glycerol, starch, cornstarch, lactose, dextrin, molasses, and the like. Preferred nitrogen sources include corn steep liquor, yeast, autolyzed brewer's yeast with milk solids, soybean meal, cottonseed meal, cornmeal, milk solids, pancreatic digest of casein, distillers' solids, animal peptone liquors, fishmeal, meat and bone scraps, and the like. Combinations of these carbon and nitrogen sources can be used advantageously. Trace metals, for example, zinc, magnesium, manganese, cobalt, and the like, usually need not be added to the fermentation media since tap water and unpurified ingredients are used as media components.

Production of lincomycin by the process of the subject invention can be effected at a temperature of about 18° to about 45° C., and preferably at a temperature of about 20° C. to about 45° C. Ordinarily, optimum production of lincomycin is obtained in about two to ten days. The final pH is dependent, in part, on the buffers present, if any, and in part on the initial pH of the culture medium.

When growth is carried out in large vessels and tanks, it is preferable to use the vegetative form, rather than the spore form, of the microorganism for inoculation to avoid a pronounced lag in the production of lincomycin and the attendant inefficient utilization of the equipment. Accordingly, it is desirable to produce a vegetative inoculum in a nutrient broth culture by inoculating this broth culture with an aliquot from a soil or a slant culture. When a young, active vegetative inoculum has thus been secured, it is transferred aseptically to large vessels or tanks. The medium in which the vegetative inoculum is produced can be the same as, or different from, that

utilized for the production of lincomycin, as long as it is such that a good growth of the microorganism is obtained.

The lincomycin produced by the subject process can be recovered by the procedure disclosed in U.S. 3,086,912.

In preferred recovery process, lincomycin is recovered from its culture medium by separation of the mycelia and undissolved solids by conventional means, such as by filtration and centrifugation. Lincomycin is then recovered from the filtered or centrifuged broth by passing said broth over a resin which comprises a non-ionic macroporous copolymer of styrene crosslinked with divinylbenzene. Resins of this type are disclosed in U.S. Patent 3,515,717. Exemplary of this type of resin is Amberlite XAD-2. Lincomycin is eluted from the resin with a solvent system consisting of methanol-water (95:5 v/v). Bioactive eluate fractions are determined by a standard microbiological disc plate assay using the microorganism *Sarcina lutea*. Biologically active fractions are combined, concentrated to an aqueous solution which is then freeze dried. The freeze dried material is then triturated with methylene chloride. The methylene chloride extract is concentrated to dryness and the residue triturated with acetone. The filtrate is mixed with ether to give a precipitate which is separated. The remaining filtrate is mixed with methanolic hydrogen chloride (1 N) to precipitate colorless lincomycin hydrochloride. This precipitate is isolated by filtration and crystallized from water-acetone to give crystalline lincomycin hydrochloride.

The process of the subject invention is not limited to the particular microorganism fully described by the cultural characteristics disclosed herein. It is intended that this invention also include other lincomycin-producing strains or mutants of the said microorganism which can be produced by procedures well known in the art, for example, by subjecting the novel microorganism to x-ray or ultraviolet radiation, nitrogen mustard, phage exposure, and the like.

Hereinafter is described a non-limiting example of the process of the present invention. All percentages are by weight and all solvent portion mixtures are by volume unless otherwise noted.

EXAMPLE 1

Part A. FERMENTATION AT 28° C.

A soil slant of *Streptomyces vellosus*, NRRL 8037, is used to inoculate a series of 500-ml. Erlenmeyer flasks containing 100-ml. of sterile seed medium consisting of the following ingredients:

Glucose monohydrate	25 g./liter
Pharmamedia *	25 g./liter
Tap water q.s.	Balance

Presterilization pH=7.2

* Pharmamedia is an industrial grade of cottonseed flour produced by Traders Oil Mill Company, Fort Worth, Texas.

The flasks are grown for 3 days at 28° C., on a rotary shaker.

Seed inoculum, described above, is used to inoculate a series of 500-ml. Erlenmeyer fermentation flasks containing 100-ml. of sterile medium consisting of the following ingredients:

Glucose monohydrate	15 g./liter
Wilson's Peptone Liquor No. 159 *	15 g./liter
Difco Yeast Extract **	2.5 g./liter
Tap water q.s.	Balance

Presterilization pH=6.0

* Wilson's Peptone Liquor No. 159 is a preparation of hydrolyzed proteins of animal origin.

** Supplied by Difco Laboratories, Detroit, Michigan.

The flasks are inoculated with 5 ml. of seed inoculum per 100 ml. of fermentation medium. The flasks are then incubated at 28° C. on a rotary shaker operating at 250 rpm with a 6 cm. stroke. The flasks are harvested after 96 hours of fermentation.

Part B. FERMENTATION at 45° C.

Seed inoculum, as described above in Part A, is used to inoculate a series of 500-ml. Erlenmeyer fermentation flasks containing 100 ml. of sterile medium consisting of the following ingredients:

Glycerol	30 g./liter
NZ-amine B *	20 g./liter
Difco Yeast Extract	2 g./liter
Sodium chloride	3 g./liter
Tap water q.s.	Balance

Presterilization pH=7.2

* A bulk peptone in powder form obtained by the pancreatic digestion of casein.

The flasks are inoculated with 5 ml. of seed inoculum per 100 ml. of fermentation medium. The flasks are then incubated at 45° C. on a rotary shaker operating at 250 rpm with a 6 cm. stroke. The flasks are harvested after 96 hours of fermentation.

Part C. RECOVERY

The lincomycin produced in the fermentations as disclosed in Parts A and B is recovered in pure form by first filtering the fermentation beers using diatomaceous earth and filter aid. The filter cake is washed with water and the wash is combined with the clear filtrate. The clear filtrate wash is then passed over a column containing Amberlite XAD-2 resin packed in water. The lincomycin is eluted from the resin with methanol-water (95:5 v/v). Fractions are collected and analyzed by thin layer chromatography on silica gel G using the solvent system consisting of methyl ethyl ketone-acetone-water (186:52:20 v/v). Active fractions are combined and concentrated to an aqueous and freeze dried. The dry material is then triturated with methylene chloride. The methylene chloride extract is concentrated to dryness. The resulting residue is triturated with acetone.

Insoluble material is removed by filtration and the remaining filtrate is mixed with ether. Again, precipitated material is removed by filtration and the remaining filtrate is mixed with methanolic hydrogen chloride (1 N). The resulting precipitated colorless lincomycin hydrochloride is isolated by filtration. This material is converted to the crystalline form by crystallization from water-acetone.

The amount of lincomycin B is a normal fermentation of *Streptomyces lincolnensis* var. *lincolnensis* will vary with the media composition, incubation time and temperature, aeration, etc. Under normal operating conditions amounts of lincomycin B in such a fermentation will range from 5 to 10% of the total lincomycin present. The lincomycin B is removed by repeated recrystallization of the lincomycin product in suitable solvents, for example, water-acetone mixtures, or water-lower alcohol mixtures. Since the process of the subject invention does not produce lincomycin B, these crystallizations are unnecessary.

CLAIMS

—1—

A novel process for preparing the antibiotic lincomycin which comprises cultivating *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, and lincomycin-producing mutants thereof, in an aqueous nutrient medium under aerobic conditions until substantial antibiotic activity is imparted to said medium by the production of lincomycin.

—2—

A process, according to claim 1, wherein the cultivation is conducted at a temperature range of about 18° C. to about 45° C.

—3—

A process, according to claim 1, wherein said aqueous nutrient medium contains a source of assimilable carbohydrate and assimilable nitrogen.

—4—

A process, according to claim 1, wherein said lincomycin is isolated from the fermentation broth.

OATH AND POWER OF ATTORNEY

Being duly sworn, We, Malcolm E. Bergy and John H. Coates and Vedpal S. Malik depose and say:

that we are citizens of U.S.A., U.S.A., and Canada, respectively residing in the City of Kalamazoo, County of Kalamazoo, State of Michigan; in the City of Kalamazoo, County of Kalamazoo, State of Michigan; in the City of Kalamazoo, County of Kalamazoo, State of Michigan, respectively,

that we have read the foregoing specification and claims and we verily believe ourselves to be the original first, and joint inventors of the invention or discovery in PROCESS described and claimed therein;

that we do not know and do not believe that this invention was ever known or used before our invention or discovery thereof, or patented or described in any printed publication in any country before our invention or discovery thereof, or more than one year prior to this application, or in public use or on sale in the United States for more than twelve months before this application; and

that this invention or discovery has not been patented in any country foreign to the United States on an application filed by us or our legal representatives or assigns more than twelve months before this application; and

that no application for patent on this invention or discovery has been filed by us or our legal representatives or assigns in any country foreign to the United States, except as follows: None.

And we hereby appoint Roman Saliwanchik and John Kekich (Registration Nos. 21,023 and 17,002, respectively), c/o Patent Law Department, The Upjohn Company, Kalamazoo, Michigan 49001 our attorney(s) or agent(s) with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent Office connected therewith.

Inventor: /s/ MALCOLM E. BERGY
Malcolm E. Bergy

Post Office Address: 2617 Lomond Drive, Kalamazoo,
Michigan 49008

Inventor: /s/ JOHN S. COATS
John H. Coats

Post Office Address: 3419 Old Colony Road, Kalamazoo,
Michigan

Inventor: /s/ VEDPAL S. MALIK
Vedpal S. Malik

Post Office Address: 821 West Lovell, Kalamazoo, Michi-
gan

STATE OF MICHIGAN
COUNTY OF KALAMAZOO, SS.

On this 6th day of June, 1974, personally appeared be-
fore me the above-named Malcolm E. Bergy and John H.
Coats and Vedpal S. Malik, the persons described in the
above application for patent, who signed the foregoing in
my presence, and made oath before me to the allegations
set forth therein as being under oath, on the day and year
aforesaid.

/s/ KENNETH L. MCCLISH
Notary Public

SEAL

My Commission Expires: March 28, 1976.

This form may be executed only when attached to a
complete application as the last page thereof.

Approved Single Signature Form
Joint Inventors
(No. 1585)

PRELIMINARY AMENDMENT, JANUARY 17, 1975

January 14, 1975

To the Commissioner
Washington, D.C. 20231

Sir:

Please amend the above-identified application as fol-
lows:

In the Claims:

Please add the following claim 5:

5. A biologically pure culture of the microorganism
Streptomyces vellosus, having the identifying characteris-
tics of NRRL 8037, said culture being capable of produc-
ing the antibiotic lincomycin in a recoverable quantity
upon fermentation in an aqueous nutrient medium con-
taining assimilable sources of carbon, nitrogen and in-
organic substances.

REMARKS

Claims 1-4 are in the case. Claim 5 is being added by
this amendment. Basis for claim 5 can be found through-
out the disclosure. The identity of the microorganism
is given in the detail description beginning on page 4
and extending through page 16.

Respectfully submitted,

/s/ ROMAN SALIWANCHIK
Roman Saliwanchik
Attorney

AMENDMENT, JANUARY 27, 1975

January 23, 1975

To the Commissioner of Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated January 20, 1975, please amend the above-identified application as follows:

In the Specification:

Page 1. Please delete the present title and insert—

PROCESS FOR PREPARING LINCOMYCIN—.

REMARKS

Claims 1-4 have been examined by the Examiner. Claim 5 was added by an amendment dated January 14, 1975, which, apparently, the Examiner had not received prior to the subject action.

The applicants are submitting, as a part of this response, an affidavit by the attorney for the applicants who attests that restrictions on availability of the micro-organism will be removed upon the granting of a patent. Further, it is attested that the culture will be maintained by the repository for the effective life of the patent. In view of this affidavit, it is respectfully requested that the Rejection under 35 USC 112 be withdrawn.

In light of the above and the amendment submitted on January 14, 1975, with the addition of claim 5, it is respectfully requested that claims 1-5 be allowed.

Respectfully submitted,

/s/ ROMAN SALIWANCHIK
Roman Saliwanchik
Attorney

AFFIDAVIT OF SALIWANCHIK

STATE OF MICHIGAN

COUNTY OF KALAMAZOO, SS.

ROMAN SALIWANCHIK, being duly sworn, deposes and says:

THAT, as attorney for the applicants, he hereby avers:

1. that all restrictions on the availability of the culture deposits disclosed in the subject patent application will be irrevocably removed on the granting of a patent for the subject application, and
2. that the cultures will be maintained in a viable state throughout the effective life of the patent, and
3. that should the repository notify the applicants that one or more of the cultures is non-viable the applicants will replace the non-viable culture with a viable culture in the repository to be maintained for the effective life of the patent which discloses the same.

FURTHER, deponent sayeth not.

/s/ ROMAN SALIWANCHIK
Roman Saliwanchik

* * * *

AFFIDAVIT OF GRADY

February 18, 1975

STATE OF MICHIGAN

COUNTY OF KALAMAZOO, SS.

JOSEPH E. GRADY, being duly sworn, deposes and says:

THAT, in 1948 I received a B.S. degree from the University of Scranton in Pennsylvania; that, in 1951 I received an M.S. degree in Bacteriology from Purdue University; that, in 1958 I received a Ph.D. degree in Bacteriology from Purdue University;

THAT, since 1958 I have been in the employ of The Upjohn Company as a microbiologist; that, my major responsibility with The Upjohn Company is in the antibiotic field; that, I have actively engaged in a program of antibiotic screening and culture development; that, I presently supervise a program of antibiotic screening and culture development; that, in this program I actively supervise the screening of microorganisms in an attempt to find new antibiotics;

THAT, I read and studied application Serial No. 477,766; and being thus qualified, further deposes and says:

The "biologically pure culture" of Claim 5 is a well-defined product of a microbiologist which is capable of producing the desired antibiotic lincomycin under controlled fermentation conditions. In contrast, the soil source in which the microorganism was discovered is a complex microbial environment which, as such, could not be used to produce a desired product under any known fermentation conditions. The microbial complexity of soils was reviewed by Dr. S. A. Waksman in his book, *The Actinomycetes Vol. 1*, The Williams & Wilkins Company, 1959, where at page 31 he states:

"At the surface of certain soils, actinomycetes, as measured by the number of colonies produced on agar plates, made up 9 to 15 percent of the total popula-

tion, or a total of 743,000 to 933,000 per gram of soil. At a depth of 30 inches, the numbers dropped to 240,000 per gram, but the percentage rose to about 66. In California soils, the numbers varied from 380,000 to 1,890,000 per gram, and the percentage of the total population from 19 to 45."

Thus, actinomycetes, which is the group of microorganisms to which the microorganism of application Serial No. 477,766 belongs, make up a significant portion of the microbial flora of soils. Further, the actinomycetes in soils themselves are complex in kind and metabolic activities. Along with the actinomycetes, soil is host for numerous other microbes, among which are bacteria and fungi.

In summary, soil contains a complex jungle of microorganisms. It is only by the discovery and skills of the microbiologist that biologically pure cultures of microorganisms come into existence. Thus, the biologically pure culture" of Claim 5 is *not* found in nature.

FURTHER deponent sayeth not.

/s/ JOSEPH E. GRADY
Dr. Joseph E. Grady

• • • •

AFFIDAVIT OF DIETZ

February 18, 1975

STATE OF MICHIGAN

COUNTY OF KALAMAZOO, SS.

ALMA DIETZ, being duly sworn, deposes and says:

THAT, I received a Bachelor of Arts degree from American International College, Springfield, Massachusetts, in 1944; that from 1944-1946 I was a lab instructor in biology at the American International College; that during the summer of 1945 I took a phycology course given at the Marine Biological Lab, Woods Hole, Massachusetts; that in the summer of 1946 I assisted in the phycology course at Marine Biological Lab; that from 1946-1948 I did graduate work in botany at the University of Michigan; that from 1948 to the present time I have been in the employ of The Upjohn Company; that my primary responsibilities with The Upjohn Company concern the maintenance and identification of actinomycete cultures; that during the course of this work I routinely study actinomycetes isolated from various sources, such as soil, in an attempt to determine whether a new species of microorganism has been discovered; that I am the author or co-author of numerous publications concerning the taxonomic features of microorganisms, particularly the streptomycetes; that I studied and characterized the biologically pure culture disclosed in application Serial No. 477,766; and being thus qualified, further deposes and says;

The taxonomic description of *Streptomyces vellosus* given in application Serial No. 477,766 was conducted on a biologically pure culture of *Streptomyces vellosus*. An impure culture of *S. vellosus* would give taxonomic results different from those given in application Serial No. 477,766. The different results would depend on the nature of the biological impurity, i.e., if it was a bacterium, another Streptomycete or a fungus. Thus, a meaningful taxonomic description, such as is given in application

Serial No. 477,766 must be done on a biologically pure culture of the microorganism.

Microorganisms found in the soil are complex in kind and cannot be taxonomically characterized without first producing a biologically pure culture. This clearly establishes that the "biologically pure culture" of Claim 5 is *not* found in nature; it is the product of a microbiologist.

FURTHER deponent sayeth not

/s/ ALMA DIETZ
Alma Dietz

• • • • •

AFFIDAVIT OF MILLER

February 18, 1975

STATE OF MICHIGAN

COUNTY OF KALAMAZOO, SS.

THOMAS L. MILLER, being duly sworn, deposes and says:

THAT, in 1961 I received an A.B. degree from Indiana State University; that, in 1963 I received a M.S. degree from the University of Wisconsin; that, in 1966 I received a Ph.D. degree from the University of Wisconsin majoring in biochemistry and minoring in bacteriology;

THAT, since 1966 I have been in the employ of The Upjohn Company initially as a Research Associate, then as a Section Head, Research Section Head, and since 1970 I have been Research Manager of Fermentation Research and Development;

THAT, I presently supervise microbiologists in the various aspects of fermentation research and development, with a large part of the work directly related to antibiotics;

THAT, I read and studied application Serial No. 477,766; and being thus qualified, further deposes and says:

The fermentation disclosed in application Serial No. 477,766 is conducted with a biologically pure culture of *S. vellosus*. A biologically *impure* culture of *S. vellosus* would *not* give the desired fermentation product under the conditions disclosed in application Serial No. 477,766, or possibly under *any* fermentation conditions. For example, if the biological impurity in a biologically *impure* culture of *S. vellosus* was a fast growing bacteria which multiplies once every 20 minutes, then little to *no* desired fermentation product could be expected. Thus, it is imperative that a biologically pure culture of *S. vellosus* be used in order to obtain the desired fermentation product using the controlled fermentation conditions disclosed in application Serial No. 477,766.

To maintain the biological purity of a culture during the propagation and fermentation stages, it is essential that operations and equipment be such that contaminants do not gain access into the system. Maintenance of sterile conditions to this extent is a major factor to the successful operation of a controlled fermentation operation.

It is clear to me that the "biologically pure culture" of Claim 5 is a product of a microbiologist and *not* a product of nature.

FURTHER, deponent sayeth not.

/s/ THOMAS L. MILLER
Dr. Thomas L. Miller

* * * *

PETITION OF APPEAL

TO THE U.S. COURT OF CUSTOMS AND PATENT APPEALS:

Applicants for patent, Malcolm E. Bergy, John H. Coats, and Vedpal S. Malik, residents of the County of Kalamazoo, State of Michigan, respectfully petition this Honorable Court for review of a decision by the United States Patent and Trademark Office Board of Appeals that the subject matter of claim 5 of their application is unpatentable under 35 U.S.C. 101 on the basis that the claim is directed to non-statutory subject matter.

Applicants respectfully reaffirm their original Oath, executed June 6, 1974, that they believe themselves to be the original and first inventors of the new process.

A complete application for patent was duly filed in the United States Patent and Trademark Office on June 10, 1974, in accordance with the Law, and the application was assigned Serial No. 477,766.

Subsequently, the Patent and Trademark Office Examiner rejected claim 5 under 35 U.S.C. 101 as drawn to non-statutory subject matter. The remaining claims 1-4 were indicated as allowable.

The Examiner's Final Rejection was appealed to the Board of Appeals which affirmed the rejection with one Board member dissenting.

By correspondence dated July 1, 1976, the applicants notified the Commissioner of Patents and Trademarks that the affirmance of the Examiner's rejection of claim 5 by the Board of Appeals was being appealed to this Honorable Court. The Notice to the Commissioner specified applicants' reasons of appeal.

By correspondence dated July 1, 1976, the applicants ordered a certified copy of the record from the Commissioner of Patents and Trademarks to be prepared and transmitted to this Honorable Court. The record will include the Notice and Reasons of Appeal.

The appeal fee of fifty (\$50.00) dollars is enclosed.

Applicants respectfully assert that the foregoing facts entitle them to an appeal before this Honorable Court; and they respectfully pray that their appeal will be heard upon and for the reasons assigned therefor.

MALCOLM E. BERGY
JOHN H. COATS
VEDPAL S. MALIK

BOARD OF APPEALS

Serial No. 260,563

Docket No. 77-535

Filed December 28, 1976

IN THE MATTER OF THE APPLICATION OF
ANANDA M. CHAKRABARTY

Counsel for appellant:

Leo I. MaLossi; Joseph B. Forman, Frank L. Neu-
hauser

Commissioner of Patents and Trademarks

DOCKET ENTRIES

DATE	PROCEEDINGS AND ORDERS
March 14, 1977	Motion of appellant to extend time for filing printed transcript to April 27, 1977, filed.
March 15, 1977	Above motion granted.
April 26, 1977	PRINTED TRANSCRIPT OF RECORD, filed.
June 2, 1977	BRIEF FOR APPELLANT, filed.
July 11, 1977	Motion to extend time for filing brief by Commissioner of patents, not to extend beyond September 23, 1977, filed.
July 18, 1977	Response by appellant to Motion by Commissioner for extension of time for filing brief, filed.
July 21, 1977	Above motion granted. The extension of time not to extend beyond September 23, 1977.
September 23, 1977	BRIEF FOR COMMISSIONER OF PATENTS & TRADEMARKS, filed.
September 28, 1977	Motion by appellant to extend time to October 24, 1977, in which to file reply brief, filed.

DATE PROCEEDINGS AND ORDERS

DATE	PROCEEDINGS AND ORDERS
September 28, 1977	Above motion granted.
October 14, 1977	Motion of appellant to extend time for filing reply brief to October 31, 1977, filed.
October 14, 1977	Above motion granted.
October 20, 1977	REPLY BRIEF FOR APPELLANT, filed.
November 4, 1977	Motion of appellant for an additional 30 minutes for oral argument, filed.
November 7, 1977	Above motion denied. Court requests counsel to file an additional brief directed to <i>Ex parte Bergy</i> on or before November 28, 1977 (25 copies in typewritten form).
November 28, 1977	BRIEF FOR APPELLANT ON REQUEST BY COURT, filed.
November 28, 1977	BRIEF FOR COMMISSIONER OF PATENTS & TRADEMARK ON REQUEST BY COURT, filed.
December 5, 1977	Argued
March 2, 1978	Reversed, Rich, Judge. Concurring opinion by Chief Judge Markey. Dissenting opinion by Judge Baldwin. Dissenting opinion by Judge Miller.
March 24, 1978	FINAL MANDATE ISSUED TO THE COMMISSIONER OF PATENTS AND TRADEMARKS
July 26, 1978	Petition for Certiorari in Supreme Court of the U.S. No. 78-145.
Aug. 3, 1978	Petition to recall mandate, vacate decision and issue a new decision affirming the Board of Appeals, filed by Commissioner of Patents.
Aug. 11, 1978	Opposition to petition to recall mandate, vacate decision and issue new decision affirming the Board of appeals, filed.

DATE	PROCEEDINGS AND ORDERS
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August 11, 1978 Above petition granted to extent that judgment is vacated, mandate recalled, and appeal restored to the calendar for hearing on November 6, 1978. Supplemental briefs to be filed as follows:

Appellant's Brief due on or before September 20, 1978.
 Commissioner's Brief due on or before October 20, 1978.
 Appellant's Reply Brief due on or before November 3, 1978.

September 18, 1978 SUPPLEMENTAL BRIEF FOR APPELLANT, filed.

September 18, 1978 BRIEF FOR AMICUS CURIAE FOR UNIVERSITY OF CALIFORNIA, filed.

September 18, 1978 Consent of Appellant and Commissioner of Patents to University of Calif. to file brief Amicus Curiae, filed.

September 20, 1978 BRIEF FOR AMICUS CURIAE FOR GENETECH, INC., filed.

September 20, 1978 BRIEF FOR AMICUS CURIAE FOR AMERICAN PATENT LAW ASS., filed.

October 19, 1978 Motion to Cornell D. Cornish for leave to file brief amicus curiae, filed.

October 19, 1978 Above motion granted, provisions of Rule 5.8 waived.

October 19, 1978 BRIEF FOR AMICUS CURIAE FOR CORNELL D. CORNISH AND THE VILLAGE OF BELLE TERRE, filed.

October 20, 1978 BRIEF FOR COMMISSIONER OF PATENTS & TRADEMARKS, filed.

October 27, 1978 Motion of Cornell D. Cornish and The Village of Belle Terre for oral argument as amicus curiae, filed.

October 27, 1978 Above motion denied.

DATE	PROCEEDINGS AND ORDERS
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November 6, 1978 Argued

March 29, 1979 Reversed, Rich, J. Concurring opinion by Judge Baldwin. Dissenting opinion by Judge Miller.

April 20, 1979 FINAL MANDATE ISSUED TO THE COMMISSIONER OF PATENTS AND TRADEMARKS

July 27, 1979 Petition for writ of certiorari filed in the Supreme Court of the United States; No. 79-136.

October 29, 1979 Petition for Writ of Certiorari, granted.

APPLICATION OF ANADA M. CHAKRABARTY,
FILED JUNE 7, 1972, SERIAL NUMBER 260,563,
FOR MICROORGANISMS HAVING MULTIPLE,
COMPATIBLE DEGRADATIVE ENERGY-GENE-
RATING PLASMIDS AND PREPARATION THERE-
OF

Abstract of the Disclosure

Unique microorganisms have been developed by the application of genetic engineering techniques. These microorganisms contain at least two stable (compatible) energy-generating plasmids, these plasmids specifying separate degradative pathways. The techniques for preparing such multi-plasmid strains from bacteria of the genus *Pseudomonas* are described. Living cultures of two strains of *Pseudomonas* (*P. aeruginosa* [NRRL B-5472] and *P. putida* [NRRL B-5473]) have been desposited with the United States Department of Agriculture, Agricultural Research Service, Northern Marketing and Nutrient Research Division, Peoria, Illinois. The *P. aeruginosa* NRRL B-5472 was derived from *Pseudomonas aeruginosa* strain 1c by the genetic transfer thereto, and containment therein, of camphor, octane, salicylate and naphthalene degradative pathways in the form of plasmids. The *P. putida* NRRL B-5473 was derived from *Pseudomonas putida* strain PpG1 by genetic transfer thereto, and containment therein, of camphor, salicylate and naphthalene degradative pathways and drug resistance factor RP-1, all in the form of plasmids.

BACKGROUND OF THE INVENTION

The terminology of microbial genetics is sufficiently complicated that certain definitions will be particularly useful in the understanding of this invention:

Extrachromosomal element . . . a hereditary unit that is physically separate from the chromosome of the cell; the terms "extrachromosomal element" and "plasmid" are synonymous; when physically separated from the chromosome, some plasmids can be transmitted at high frequency to other cells, the

transfer being without associated chromosomal transfer;

Episome . . . a class of plasmids that can exist in a state of integration into the chromosome of their host cell or as an autonomous, independently replicating, cytoplasmic inclusion;

Transmissible plasmid . . . a plasmid that carries genetic determinants for its own intercell transfer via conjugation;

DNA . . . deoxyribonucleic acid;

Bacteriophage . . . a particle composed of a piece of DNA encoded and contained within a protein head portion and having a tail and tail fibers composed of protein;

Transducing phage . . . a bacteriophage that carries fragments of bacterial chromosomal DNA and transfers this DNA on subsequent infection of another bacterium;

Conjugation . . . the process by which a bacterium establishes cellular contact with another bacterium and the transfer of genetic material occurs;

Curing . . . the process by which selective plasmids can be eliminated from the microorganism;

Curing agent . . . a chemical material or a physical treatment that enhances curing;

Genome . . . a combination of genes in some given sequence;

Degradative pathway . . . a sequence of enzymatic reactions (e.g. 5 to 10 enzymes are produced by the microbe) converting the primary substrate to some simple common metabolite, a normal food substance for microorganisms;

(Sole carbon source)—. . . indicative of a mutant incapable of growing on the given sole carbon source;

(Plasmid) del . . . indicative of cells from which the given plasmid has been completely driven out by

curing or in which no portion of the plasmid ever existed;

(Plasmid) . . . indicative of cells lacking in the given plasmid; or cells harboring a non-functional derivative of the given plasmid;

(Amino-acid)— . . . indicative of a strain that cannot manufacture the given amino acid;

(Vitamin)— . . . indicative of a strain that cannot manufacture the given vitamin and

(Plasmid) + . . . indicates that the cells contain the given plasmid.

Plasmids are believed to consist of double-stranded DNA molecules. The genetic organization of a plasmid is believed to include at least one replication site and a maintenance site for attachment thereof to a structural component of the host cell. Generally, plasmids are not essential for cell viability.

Much work has been done supporting the existence, functions and genetic organization of plasmids. As is reported in the review by Richard P. Novick "Extrachromosomal Inheritance in Bacteria" (Bacteriological Reviews, June 1969, pp. 210-263, [1969]) on page 229, "DNA corresponding to a number of different plasmids has been isolated by various methods from plasmid-positive cells, characterized physicochemically and in some cases examined in the electron microscope".

There is no recognition in the Novick review of the existence of energy-generating plasmids specifying degradative pathways. As reported on page 237 of the Novick review, of the known (non energy-generating) plasmids "Combinations of four or five different plasmids in a cell seem to be stable."

Plasmids may be compatible (i.e. they can reside stably in the same host cell) or incompatible (i.e. they are unable to reside stably in a single cell). Among the known plasmids, for example, are sex factor plasmids and drug-resistance plasmids.

Also, as stated on page 240 of the Novick review, "Cells provide specific maintenance systems or sites for plasmids.

It is thought that attachment of such sites is required for replication and for segregation of replicas. Each plasmid is matched to a particular maintenance site . . .". Once a plasmid enters a given cell, if there is no maintenance site available, because of prior occupancy by another plasmid, these plasmids will be incompatible.

The biodegradation of aromatic hydrocarbons such as phenol, cresols and salicylate has been studied rather extensively with emphasis on the biochemistry of these processes, notably enzyme characterization, nature of intermediates involved and the regulatory aspects of the enzymic actions. The genetic basis of such biodegradation, on the other hand, has not been as thoroughly studied because of the lack of suitable transducing phages and other genetic tools.

The work of Chakrabarty and Gunsalus (Genetics, 68, No. 1, page S10, [1971]) has showed that the genes governing the synthesis of the enzymes responsible for the degradation of camphor constitute a plasmid. Similarly, this work has shown the plasmid nature of the octane-degradative pathway. However, attempts by the authors to provide a microorganism with both CAM and OCT plasmids were unsuccessful, these plasmids being incompatible.

In *Escherichia coli* artificial, transmissible plasmids (one per cell) have been made, each containing a degradative pathway. These plasmids, not naturally occurring, are F'*lac* and F'*gal*, wherein the lactose- and galactose-degrading genes were derived from the chromosome of the organism. Such plasmids are described in "F-prime Factor Formation in *E. Coli* K12" by J. Scaife (Genet. Res. Cambr. [1966], 8, pp. 189-196).

If the development of microorganisms containing multiple compatible energy-generating plasmids specifying preselected degradative pathways could be made possible, the economic and environmental impact of such an invention would be vast. For example, there would be immediate application for such versatile microbes in the production of proteins from hydrocarbons ("Proteins from Petroleum"—Wang, Chemical Engineering, August 26, 1968, page 99); in cleaning up oil spills ("Oil Spills: An

Environmental Treat"—Environmental Science and Technology, Volume 4, February 1970, page 97); and in the disposal of used automotive lubricating oils ("Waste Lube Oils Pose Disposal Dilemma", Environmental Science and Technology, Volume 6, page 25, January 1972).

SUMMARY OF THE INVENTION

A transmissible plasmid has been found that specifies a degradative pathway for salicylate [SAL], an aromatic hydrocarbon. In addition, a plasmid has been identified that specifies a degradative pathway for naphthalene [NPL], a polynuclear aromatic hydrocarbon. The NPL plasmid is also transmissible.

Having established the existence of (and transmissibility of) plasmid-borne capabilities for specifying separate degradative pathways for salicylate and naphthalene, unique single-cell microbes have been developed containing various stable combinations of the [CAM], [OCT], [SAL], and [NPL] plasmids. In addition, stable combinations in a single cell of the aforementioned plasmids together with a non energy-generating plasmid [drug resistance factor RP-1] have been achieved. The versatility of these novel microorganisms has been demonstrated by the substantial extent to which degradation of such complex hydrocarbons as crude oil and Bunker C oil has been achieved thereby.

BRIEF DESCRIPTION OF THE DRAWING

The exact nature of the invention as well as objects and advantages thereof will be readily apparent from consideration of the following specification relating to the annexed drawing in which:

Fig. 1 shows the increase in growth rate in crude oil of *Pseudomonas* strain bacteria provided with increasing numbers of energy-generating degradative plasmids by the practice of this invention and

Fig. 2 shows the increase in growth rate in Bunker C oil of *Pseudomonas* strain bacteria provided with in-

creasing numbers of energy-generating degradative plasmids by the practice of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Microorganisms prepared by the genetic engineering processes described herein are exemplified by cultures now on deposit with the United States Department of Agriculture. These cultures are identified as follows:

Pseudomonas aeruginosa (NRRL B-5472) . . . derived from *Pseudomonas aeruginosa* strain 1c (ATCC No. 15692) by genetic transfer thereto, and containment therein, of camphor, octane, salicylate and naphthalene degradative pathways in the form of plasmids.

Pseudomonas putida (NRRL B-5473) . . . derived from *Pseudomonas putida* strain PpG1 (ATCC No. 17453) by genetic transfer thereto, and containment therein, of camphor, salicylate and naphthalene degradative pathways and a drug resistance factor RP-1, all in the form of plasmids. The drug resistance factor is responsible for resistance to neomycin/kanamycin, carbenicillin and tetracycline.

A sub-culture of each of these strains can be obtained from the permanent collection of the Northern Marketing and Nutrient Research Division, Agricultural Service, U.S. Department of Agriculture, Peoria, Illinois, U.S.A.

Morphological observations in various media, growth in various media, general group characterization tests, utilization of sugars and optimum growth conditions for the strains from which the above-identified organisms were derived are set forth in "The Aerobic Pseudomonads: A Taxonomic Study" by Stanier, R. Y. et al [Journal of General Microbiology 43, pp. 159-271 (1966)]. The taxonomic properties of the above-identified organisms remain the same as those of the parent strains. *P. aeruginosa* strain 1c (ATCC No. 15692) is the same as strain 131 (ATCC No. 17503) in the Stanier et al study.

Later the designation for this strain was changed to *P. aeruginosa* PAO [Holloway, B. W. "Genetics of *Pseudomonas*", Bacteriological Reviews 33, 419-443 (1969)]. *P. putida* strain PpG1 (ATCC No. 17453) is the same as strain 77 (ATCC No. 17453) in the Stanier et al study.

As will be described in more detail hereinbelow, these organisms thrive on a very wide range of hydrocarbons including crude oil and Bunker C oil. These organisms are non-pathogenic as is the general case with laboratory strains of *Pseudomonas*.

In brief, the process for preparing microbes containing multiple compatible energy-generating plasmids specifying separate degradative pathways is as follows:

- 1) selecting the complex or mixture to be degraded;
- 2) identifying the plurality of degradative pathways required in a single cell to degrade the several components of the complex or mixture therewith;
- 3) isolating a strain of some given microorganism on one particular selective substrate identical or similar to one of the several components (the selection of the microorganism is generally on the basis of a demonstrated superior growth capability);
- 4) determining whether the capability of the given strain to degrade the selective substrate is plasmid-borne;
- 5) attempting to transfer this first degradative pathway by conjugation to other strains of the same organism (or to the same strain which has been cured of the pathway) and then verifying the transmissible nature of the plasmid;
- 6) purifying the conjugatants (recipients of the plasmids by conjugation) and checking for distinctive characteristics of the recipient to insure that the recipient did, in fact, receive the degradative pathway;
- 7) repeating the process so as to introduce a second plasmid to the conjugatants;

8) rendering the first and second plasmids compatible, if necessary, by fusion of the plasmids and

9) repeating the process as outlined above until the full complement of degradative pathways desired in a single cell has been accomplished by plasmid transfer (and fusion, when required).

In the first reported instance (Chakrabarty et al article mentioned hereinabove) in which the attempt was made to locate more than one energy-generating degradative pathway in the same cell, it was found that CAM and OCT plasmids cannot exist stably under these conditions. In spite of the implication from these results that multiple energy-generating plasmid content in a single cell could be achieved but not maintained, it was decided to attempt to discover some way in which to overcome this problem of plasmid incompatibility. As noted hereinabove and described more fully hereinbelow with specific reference to energy-generating plasmid transfer in the genus *Pseudomonas*, the problem of plasmid instability has now been solved by bringing about fusion of the plasmids in the recipient cell.

The development of single cell capability for the degradation and conversion of complex hydrocarbons was selected as the immediate beneficial application with particular emphasis on the genetic control of oil spills by the use of a single strain of *Pseudomonas*. In order to be able to cope with crude oil and Bunker C oil spills it was decided that the single cell of *Pseudomonas* derivative produced by this invention should possess degradative pathways for linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic hydrocarbons. *Pseudomonas aeruginosa* (NRRL B-5472) strain, which displays these degradative capabilities was thereupon eventually developed.

Massive oil spills that are not promptly contained and cleaned up have a catastrophic effect on aquatic lives. Microbial strains are known that can decompose individual components of crude oil (thus, various yeasts can degrade aliphatic straight-chain hydrocarbons, but not most of the aromatic and polynuclear hydrocarbons). *Pseudomonas* and other bacteria species are known to de-

grade the aliphatic, aromatic and polynuclear aromatic hydrocarbon compounds, but, unfortunately any given strain can degrade only a particular component. For this reason, prior to the instant invention, biological control of oil spills had involved the use of a mixture of bacterial strains, each capable of degrading a single component of the oil complex on the theory that the cumulative degradative actions would consume the oil and convert it to cell mass. This cell mass in turn serves as food for aquatic life. However, since bacterial strains differ from one another in a) their rates of growth on the various hydrocarbon components, b) nutritional requirements, production of antibiotics or other toxic material, and c) requisite pH, temperature and mineral salts, the use of a mixed culture leads to the ultimate survival of but a portion of the initial collection of bacterial strains. As a result, when a mixed culture of hydrocarbon-degrading bacteria are deposited on an oil spill the bulk of the oil often remains unattacked for a long period of time (weeks) and is free to spread or sink.

By establishing that SAL and NPL degradative pathways are specified by genes borne by transmissible plasmids in *Pseudomonas* and by the discovery that plasmids can be rendered stable (e.g. CAM and OCT) by fusion of the plasmids it has been made possible, for the first time, to genetically engineer a strain of *Pseudomonas* having the single cell capability for multiple separate degradative pathways. Such a strain of microbes equipped to simultaneously degrade several components of crude oil can degrade an oil spill much more quickly (days) than a mixed culture meanwhile bringing about coalescence of the remaining portions into large drops. This action quickly removes the opportunity for spreading of the oil thereby enhancing recovery of the coalesced residue.

Preparation of *P. aeruginosa* [NRRL B-5472]

The compositions of the synthetic mineral media for growth of the cultures were the same for all the *Pseudomonas* species employed. The mineral medium was prepared from:

PA Concentrate	100 ml of 1 Molar K_2HPO_4 , 50 ml of 1 Molar KH_2PO_4 , 160 ml of 1 Molar NH_4Cl
100 X Salts	19.5 gm $MgSO_4$, 5.0 gm $MnCO_3 \cdot H_2O$ 5.0 gm $FeSO_4 \cdot 7H_2O$ 0.3 gm $CaCl_2 \cdot 2H_2O$ 1.0 gm Ascorbic acid 1 liter H_2O

Each of the above (PA Concentrate and 100 X Salts) was sterilized by autoclaving. Thereafter, one liter of the mineral medium was prepared as follows:

PA Concentrate	77.5 ml
100 X Salts	10.0 ml
Agar	15.0 gm
H_2O	to one liter (The pH is adjusted to 6.8-7.0).

All experiments were carried out at 32°C unless otherwise stated.

It was decided that a very useful hydrocarbon degradation capability would be attained in a single *Pseudomonas aeruginosa* cell, if the degradative pathways for linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic hydrocarbons could be transferred thereto. *Pseudomonas aeruginosa* PAO was selected because of its high growth rate even at temperatures as high as 45°C. Four strains of *Pseudomonas* were selected having the individual capabilities for degrading n-octane (a linear aliphatic hydrocarbon), camphor (a cyclic aliphatic hydrocarbon), salicylate (an aromatic hydrocarbon) and naphthalene (a polynuclear aromatic hydrocarbon).

The specific strains of *Pseudomonas* able to degrade these hydrocarbons were then treated with curing agent to verify the plasmid-nature of each of these degradative pathways. Of the known curing agents (e.g. sodium dodecyl sulfate, urea, acriflavin, rifampicin, ethidium bromide, high temperature, mitomycin C, acridine orange etc.) most were unable to cure any of the degradative

pathways. However, it is found (Table I) that the degradative pathways of the several species could be cured with mitomycin C. Each of the *Pseudomonas* strains bearing the specified degradative pathways are known in the art:

- a) CAM+ *P. putida* PpGl . . . Proc. Nat. Acad. Sci. (U.S.A.), 60, 168 (1968)
- b) OCT+ *P. oleovorans* . . . J. Biol. Chem. 242, 4334 (1967)
- c) SAL+ *P. putida* R-1 . . . Bacteriological Proceedings 1972 p. 60
- d) NPL+ *P. aeruginosa* . . . Biochem. J. 91, 251 (1964)

TABLE I

	Strain	Degradative Pathway	Mitomycin C Concentration (μ g/ml)	Frequency of Curing (Percent)
CAM ⁺	<i>P. putida</i> PpGl	cyclic aliphatic hydrocarbon (camphor)	0 10 20	< 0.01 5 95
OCT ⁺	<i>P. oleovorans</i>	aliphatic hydrocarbon (n-octane)	0 10 20	< 0.1 1.0 3.0
SAL ⁺	<i>P. putida</i> R-1	aromatic hydrocarbon (salicylate)	0 5 10 15	< 0.1 0.7 3.0 4.0
NPL ⁺	<i>P. aeruginosa</i>	polynuclear aromatic hydrocarbon (naphthalene)	0 5 10	< 0.1 0.5 1.8

Curing degradative pathways from each strain with mitomycin C was accomplished by preparing several test tubes of L broth [Lennox E.S. (1955), *Virology*, 1, 190] containing varying concentrations of mitomycin C and inoculating these tubes with suitable dilutions of early stationary phase cells of the given strain to give concentrations 10^4 to 10^5 cells/ml. These tubes were incubated on a shaker at 32°C . for 2-3 days. Aliquots from tubes that showed some growth were then diluted and plated on glucose minimal plates. After growth at 32°C for 24 hours, individual colonies were split and respotted on glucose-minimal and degradative pathway—minimal plates to give the proportion of CAM—, OCT—, SAL— and NPL— in order to determine the frequency of curing. It was, therefore, shown that in each instance the degradative pathway genes are plasmidborne.

Transductional studies with a number of point mutants in the camphor and salicylate pathways has suggested that the cured segments lost either the entire or the major portion the plasmid genes. The plasmid nature of the degradative pathways was also confirmed from evidence of their transmissibility by conjugation from one strain to another (Table II). Although the frequency of plasmid transfer varies widely with individual plasmids and although OCT plasmid cannot be transferred from *P. oleovorans* to *P. aeruginosa* PAO at any detectable frequency, most of the plasmids can nevertheless be transferred from one strain to another by conjugation.

The plasmid transfers, instead of being made to other strains could have been made to organisms of the same strain, that had been cured of the given pathway with mitomycin C, acridine orange or other curing agent.

Pseudomonas putida U has been described in the article by Feist et al [*J. Bacteriology* 100, p. 869-877 (1969)].

The auxotrophic mutants (mutants that require a food source containing a particular amino acid or vitamin for growth) shown in Table II as donors were each grown in a complex nutrient medium (e.g. L broth) to a population density of at least about 10^8 cells/ml without shak-

ing in a period of from 6 to 24 hours. The prototropic (cells capable of growing on some given minimal source of carbon) recipients to which degradative pathway transfer was desired were grown separately in the same complex nutrient medium to a population density of at least about 10^8 cells/ml with shaking in a period of from 4 to 26 hours. For each degradative pathway transfer these cultures were mixed in equal volumes, kept for 15 minutes to 2 hours at 32°C without shaking (to permit conjugation to occur) and then plated on minimal plates containing the particular substrate as the sole source of carbon. This procedure for cell growth of donor and recipient and the mixing thereof is typical of the manner in which conjugation and plasmid transfer is encouraged in the laboratory, this procedure being designed to provide a very efficient transfer system. Temperature is not critical, but the preferred temperature range is $30-37^\circ\text{C}$. Reduction in the population density of either donor or recipient below about 1,000,000 cells/ml or any change in the optimal growth conditions (stationary growth of donor, agitated growth of recipient, growth in high nutrient content medium, harvest of recipient cells at log phase) will drastically reduce the frequency of plasmid transfer.

The details for preparing and isolating auxotrophic mutants is described in the textbook, "The Genetics of Bacteria and Their Viruses" by William Hays [John Wiley & Sons, Inc. (1965)].

TABLE II

Donor	Recipient	Degradative Pathway	Frequency of Transfer
Trp ⁻ CAM ⁺ <u>P. putida</u> PpG1	<u>P. aeruginosa</u> PAO CAM ^{del} <u>P. putida</u>	CAM CAM	10 ⁻³ 10 ⁻²
Met ⁻ OCT ⁺ <u>P. oleovorans</u>	<u>P. aeruginosa</u> PAO <u>P. putida</u> PpG1 <u>P. putida</u> U	OCT OCT OCT	< 10 ⁻⁹ 10 ⁻⁹ 10 ⁻⁷
His ⁻ SAL ⁺ <u>P. putida</u> R-1	<u>P. aeruginosa</u> PAO <u>P. putida</u> PpG1	SAL SAL	10 ⁻⁷ 10 ⁻⁶
Trp ⁻ NPL ⁺ <u>P. aeruginosa</u>	<u>P. putida</u> PpG1 NPL ^{del} <u>P. aeruginosa</u> PAO	NPL NPL	10 ⁻⁷ 10 ⁻⁵

Abbreviations:

Trp - tryptophane
Met - methionine
His - histidine

Control cultures of donors and recipients were also placed individually on minimal plates containing the requisite substrate in each instance as the sole source of carbon, to determine the reversion frequency of donor and recipient cells.

All plates (including controls) were incubated at 30-37°C for several days. In each instance in which colonies appeared in numbers exceeding the colony growth on the reversion plates, it was established that degradative pathway transfer had occurred between the donors and recipients. Such conjugatants were then purified by a series of single colony isolation cultures and checked for growth rates or other distinctive characteristics of the recipient to insure that the recipient actually received the given degradative pathway.

Having determined that the degradative pathways were plasmid-borne and transmissible, the task of transferring the multiplicity of plasmids to a single cell *P. aeruginosa* PAO was undertaken. Prior work (referred to hereinabove) had established that OCT plasmids could not be transferred from *P. oleovorans* to *P. aeruginosa* PAO. Therefore, the first task was to discover how (if at all) the OCT and CAM plasmids could be rendered compatible.

The CAM plasmid was transferred to a Met⁻ mutant of OCT⁺ *P. oleovorans* strain from a CAM⁺ *P. putida* strain. The conjugatant is, of course, unstable and will segregate either CAM or OCT at an appreciable rate. Therefore, the conjugatant was alternatively grown in camphor and then octane as sole sources of carbon to isolate those cells in which both of these degradative pathways were present, even though unstable. The surviving cells were centrifuged, suspended in 0.9% saline solution and irradiated with UV rays (3 General Electric FS-5 lamps providing a total of about 24 watts). Aliquots were drawn from the suspension as follows: one aliquot was removed before UV treatment, one aliquot after UV exposure for 30 seconds and one aliquot after UV exposure for 60 seconds. These aliquots of irradiated cells were grown in the absence of light for 3 hours in L broth and were then used as donors for the transfer of plasmids to the *P. aeruginosa* PAO strain

as recipient, selection being made for the OCT plasmid on an octane minimal plate.

As is shown in Table III aliquots of similarly irradiated suspensions for Met—OCT+CAM^{del} *P. oleovorans* and Met—CAM+OCT^{del} *P. oleovorans* were prepared and used as plasmid donors to *P. aeruginosa* PAO, selection being made for the plasmids shown. The Met—CAM+OCT^{del} strain was prepared by introducing CAM plasmids into Met—OCT+ mutant of *P. oleovorans* and selecting for CAM+ conjugatants, which have lost the OCT plasmid. The Met—OCT+CAM^{del} *P. oleovorans* is the Met—mutant of wild type *P. oleovorans*.

The failure to secure determinable transfer of OCT plasmids from Met—OCT+*P. oleovorans* to the recipient and the success in securing transfer of CAM plasmids from Met—CAM+OCT^{del} *P. oleovorans* to the recipient are shown. These results support the theory that the successful transfer of OCT plasmids from the MET—CAM+OCT+ *P. oleovorans* (that had been irradiated for 30 seconds with UV rays) to *P. aeruginosa* PAO had been made possible by the fusion of the CAM and OCT plasmids in the *P. oleovorans* by the UV exposure and the subsequent transfer of CAM/OCT plasmids in combination (with separate degradative pathways) to the recipient.

TABLE III

Donor	Recipient	Selected Plasmid	Period of UV-Irradiation (Sec)	Transfer of Frequency
Met ⁺ OCT ⁺ <i>P. oleovorans</i>	<i>P. aeruginosa</i> PAO	OCT	0 30 60	< 10 ⁻⁹ < 10 ⁻⁹ < 10 ⁻⁹
Met ⁺ CAM ⁺ OCT ^{del} <i>P. oleovorans</i>	<i>P. aeruginosa</i> PAO	CAM	0 30 60	10 ⁻⁴ 10 ⁻⁵ 10 ⁻⁷
Met ⁺ CAM ⁺ OCT ⁺ <i>P. oleovorans</i>	<i>P. aeruginosa</i> PAO	OCT	0 30 60	< 10 ⁻⁹ 10 ⁻⁸ < 10 ⁻⁹

Table IV presents verification of this theory of co-transfer of CAM and OCT fused plasmids. A Trp⁻ mutant of CAM⁺OCT⁺ *P. aeruginosa* PAO that had been provided with its multiple plasmids by the methods described herein for plasmid transfer and plasmid fusion was used as the donor. After conjugation between the donor and OCT^{del} CAM^{del} *P. putida* PpG1, the resulting culture was plated on minimal plates containing camphor and also on minimal plates containing n-octane. Part of each of 132 colonies growing on the CAM minimal plates were transferred to OCT minimal plates and part of each of 219 colonies growing on the OCT minimal plates were transferred to CAM minimal plates. Each of these transferred portions grew, which tends to establish that a) both CAM and OCT plasmids had been transferred to the conjugatant, b) the transfer had been on a one-for-one basis and, therefore, c) the CAM and OCT plasmids were fused together.

Similar plasmid transfer was carried out between the Trp⁻CAM⁺OCT⁺ *P. aeruginosa* PAO donor and OCT^{del} CAM^{del} *P. aeruginosa* PAO and similar selection procedures were employed. The results further reinforced the above position as to the fused nature of the transferred CAM and OCT plasmids. When the CAM and OCT plasmids have been subjected to UV radiation as disclosed, if either CAM or OCT plasmid is transferred, the other plasmid will always be associated with it regardless of which plasmid is selected first. If either plasmid of the fused pair is cured from the cell, both plasmids are lost simultaneously. Thus, the conjugatants were treated with mitomycin C and the resultant CAM^{del} segregants were examined. Invariably all CAM^{del} segregants were found to have lost the OCT plasmid as well. Thus, the facts of simultaneous curing of the two plasmids and the co-transfer thereof strongly suggests that incompatible plasmids treated with means for cleaving the DNA of the plasmids results in fusion of the DNA segments to become part of the same replicon.

TABLE IV

Donor	Recipient	Selected Plasmid	Non-selected Plasmid	Total + OCT/CAM
Trp ⁻ CAM ⁺ OCT ⁺	OCT ^{del} CAM ^{del}	CAM	OCT	132/132
<i>P. aeruginosa</i> PAO	<i>P. putida</i> PpG1	OCT	CAM	219/219
	OCT ^{del} CAM ^{del}	CAM	OCT	107/107
	<i>P. aeruginosa</i> PAO	OCT	CAM	96/96

Having successfully overcome all obstacles to the formation of a stable CAM+OCT+SAL+NPL+ *Pseudomonas* the several energy-generating degradative plasmids were transferred to a single cell as is shown in Table V by the conjugation techniques described hereinabove. The initial *P. aeruginosa* strain used is referred to herein as *P. aeruginosa* PAO, formerly known as *P. areuginosa* strain 1c available as ATCC No. 15692 and/or ATCC No. 17503. This strain of *P. aeruginosa* does not contain any known energy-generating plasmid. The CAM and OCT plasmids exist in the fused state, are individually and simultaneously functional and appear perfectly compatible with the individual compatible SAL and NPL plasmids. Tests for compatibility of both CAM+OCT+SAL+ *P. aeruginosa* PAO and CAM+OCT+SAL+NPL+ *P. aeruginosa* PAO revealed that there is no segregation of the plasmids in excess of that found in the donor. Plasmids will be accepted and maintained by *P. acidovorans*, *P. alcaligenes* and *P. fluorescens*. All of these plasmids should be transferable to and maintainable in these and many other species of *Pseudomonas*, such as *P. putida*, *P. oleovorans*, *P. multivorans*, etc.

Superstrains such as the CAM+OCT+SAL+NPL+ strain of *P. aeruginosa* PAO can grow on a minimal plate of any of camphor, n-octane, salicylate, naphthalene and, because of the phenomenon of relaxed specificity, on compounds similar thereto. Thus, the effectiveness of a given degradative plasmid does not appear to be diminished in its ability to function singly by the presence of other degradative plasmids in the same cell.

TABLE V

Donor	Recipient	Selected Plasmid	Phenotype of the Conjugant
Trp ⁺ CAM ⁺ OCT ⁺ <i>P. aeruginosa</i> PAO	<i>P. aeruginosa</i> PAO	CAM	CAM ⁺ OCT ⁺ <i>P. aeruginosa</i> PAO
His ⁺ SAL ⁺ <i>P. putida</i> R-1	CAM ⁺ OCT ⁺ <i>P. aeruginosa</i> PAO	SAL	CAM ⁺ OCT ⁺ SAL ⁺ <i>P. aeruginosa</i> PAO
Trp ⁺ NPL ⁺ <i>P. aeruginosa</i>	CAM ⁺ OCT ⁺ SAL ⁺ <i>P. aeruginosa</i> PAO	NPL	CAM ⁺ OCT ⁺ SAL ⁺ NPL ⁺ <i>P. aeruginosa</i> PAO

Indication of the capability of all degradative plasmids to function simultaneously in energy generation is provided by tests in which CAM+OCT+SAL+NPL+ *P. aeruginosa* PAO superstrain was added to separate broth samples each of which contained 1 millimolar (mM) of nutrient (a suboptimal concentration), one set of samples containing camphor, a second set of samples containing n-octane, a third set of samples containing salicylate and a fourth set of samples containing naphthalene, these being the sole sources of carbon in each instance. The superstrain grew very slowly in the separate sole carbon source samples. However, when the superstrain was added to samples containing all four sources of carbon present together in the same (1 mM) concentration of 4 mM, the rate of growth increased considerably establishing that simultaneous utilization of all four sources of carbon had occurred.

Next, the ability of such superstrains to degrade crude oil was demonstrated. Crude oils, of course, vary greatly (depending upon source, period of activity of the well, etc.) in the relative amount of linear aliphatic, cyclic aliphatic, aromatic and polynuclear hydrocarbons present, although some of each of these classes of hydrocarbons is typically present in some amount in the chemical make up of all crude oils from producing wells.

Fig. 1 shows the difference in growth capabilities in crude oil as the sole source of carbon of four single cell strains of *P. aeruginosa* PAO. Curve *a* shows the cell growth as a function of time of *P. aeruginosa* without any plasmid-borne energy-generating degradative pathways. Curve *b* shows greater cell growth as a function of time for SAL+ *P. aeruginosa*. Curve *c* shows still greater cell growth as a function of time for SAL+ NPL+ *P. aeruginosa*. Curve *d* shows cell growth that is significantly greater still as a function of time for the CAM+OCT+SAL+NPL+superstrain of *P. aeruginosa*. These results clearly establish that cells artificially provided by the practice of this invention with the genetic capability for degrading different hydrocarbons can grow at a faster rate and better on crude oil as the plasmid-borne degradative pathways are increased in number and

variety, because of the facility of these degradative pathways to simultaneously function at full capacity.

Similar results are shown in Fig. 2 displaying the growth capabilities of this same series of organisms utilizing Bunker C oil as the sole source of carbon. Bunker C is (or is prepared from) the residuum remaining after the more commercially useful components have been removed from crude oil. This residuum is very thick and sticky and without significant use, per se. A small amount of volatile hydrocarbons is often added thereto to lower the viscosity. Curve *r* reflects the cell growth as a function of time of *P. aeruginosa* cells not having any plasmid-borne energy-degradative pathways. Curve *s* shows increased cell growth as a function of time for SAL+ *P. aeruginosa*. Curve *t* shows further increase in cell growth as a function of time for SAL+ NPL+ *P. aeruginosa*. Curve *u* shows still more significant cell growth as a function of time for CAM+ OCT+ SAL+ NPL+ *P. aeruginosa*.

The SAL+ *P. aeruginosa* and SAL+ NPL+ *P. aeruginosa* cultures were prepared as shown in Table VI below:

TABLE VI

<u>Donor</u>	<u>Recipient</u>	<u>Selected Plasmid</u>	<u>Conjugant</u>
His ⁻ SAL ⁺ <u>P. putida R-1</u>	<u>P. aeruginosa PAO</u>	SAL	SAL ⁺ <u>P. aeruginosa PAO</u>
Trp ⁻ NPL ⁺ <u>P. aeruginosa</u>	SAL ⁺ <u>P. aeruginosa PAO</u>	NPL	SAL ⁺ NPL ⁺ <u>P. aeruginosa PAO</u>

The experiments providing the data for Figs. 1 and 2 were conducted in 250 ml Erlenmeyer flasks. To each flask was added 50 ml of mineral medium (described hereinabove) with pH adjusted to 6.8—7.0; 2.5 ml of the sole carbon source (crude oil or Bunker C) and 5×10^6 — 1×10^7 cells. Growth was conducted at 32°C with shaking. At daily intervals 5 ml aliquots were taken. The optical densities of these aliquots were determined at 660 nm in a Bausch & Lomb, Inc. colorimeter to determine organism density. Also, viable cell counts were determined by diluting portions of the aliquots and plating on L-agar (L-broth containing agar) plates. The colonies were counted after 24 hours of incubation at 32°C and these counts were used to construct Figs. 1 and 2. Also, the cells were submitted to protein analysis, to be discussed hereinbelow.

The 2.5 ml of crude oil or Bunker C appears to have initially offered an essentially unlimited food supply, but the results shown may well represent less than the full capability of the superstrain, because the relative amounts of the various hydrocarbons (degradable by the CAM⁺, OCT⁺, SAL⁺ and NPL⁺ plasmids) present in the carbon sources had not been ascertained and after a couple of days the food supply for one or more plasmids may have been limited.

A very significant aspect of the growth of the superstrain in crude and Bunker C oils is the fact that the components, which would spread the quickest on the water's surface from spills of these oils, disappear within 2-3 days and the remaining components of the oil coalesce to form large droplets that cannot spread out. These droplets can be removed more easily by mechanical recovery techniques as the microbes continue to consume these remaining components.

In practice in inoculum of dry (or lyophilized) powders of these genetically engineered microbes will be dispersed over (e.g. from overhead) an oil spill as soon as possible to control spreading of the oil, which is so destructive of marine flora and fauna and the microbes will degrade as much of the oil as possible to reduce the amount that need be recovered mechanically, when equipment has

reached the scene and has been rendered operative. A particularly beneficial manner of depositing the inoculum on the oil spill is to impregnate straw with the inoculum and drop the inoculated straw on the oil spill where both components will be put to use—the inoculum (mass of microbes) to degrade the oil and the straw to act as a carrier for the microbes and also to function as an oil absorbent. Other absorbent materials may be used, if desired, but straw is the most practical. No special care need be taken in the preparation and storage of the dried inoculum or straw (or other absorbent material) coated with inoculum. No additional nutrient or mineral content need be supplied. Also, although culture from the logarithmic growth phase is preferred, culture from either the early stationary or logarithmic growth phases can be used.

It is reasonable to expect that a vast number of plasmid-borne hydrocarbon degradative pathways remain undiscovered. Hopefully, now that a method for controlled genetic additions to the natural degradative capabilities of microbes has been demonstrated by this invention, still more new and useful single cell organisms can be prepared able to degrade even more of the large number of hydrocarbons in crude oil, whether or not the plasmids yet to be found are compatible with each other or with those plasmids present in superstrains NRRL B-5472 and NRRL B-5473.

Both of these superstrains can be used as recipients for more plasmids. The capability for utilizing fusion (by UV irradiation or X-ray exposure) to render additional plasmids compatible is actually increased in a multi-plasmid conjugatant, because of the larger selection of stable plasmids to which the newly introduced plasmid can be fused.

Preparation of *P. putida* [NRRL B-5473]

The mineral medium and the technique for fostering conjugation was the same as described above. A culture of antibiotic-sensitive *P. putida* PpG1 was cured of its CAM plasmids with mitomycin C and was used as the

initial recipient. This strain of *P. putida* is sensitive to small (e.g. 25 micrograms/ml) concentrations of neomycin/kanamycin, carbenicillin and tetracycline. As is shown in Table VII below, all the donor strains are auxotrophic mutants, because the use of auxotrophic mutant donors facilitates counterselection of the conjugatants due to the ease of selecting against such donors.

TABLE VII

Donor	Recipient	Selected Plasmid	Phenotype of the Conjugant
Trp ⁻ CAM ⁺ <u>P. putida</u> PpG1	CAM ^{del} <u>P. putida</u> PpG1	CAM	CAM ⁺ <u>P. putida</u> PpG1
His ⁻ SAL ⁺ <u>P. putida</u> R-1	CAM ⁺ <u>P. putida</u> PpG1	SAL	CAM ⁺ SAL ⁺ <u>P. putida</u> PpG1
Trp ⁻ NPL ⁺ <u>P. aeruginosa</u>	CAM ⁺ SAL ⁺ <u>P. putida</u> PpG1	NPL	CAM ⁺ SAL ⁺ NPL ⁺ <u>P. putida</u> PpG1
Met ⁻ <u>P. aeruginosa</u> Strain 1822 (RP-1)	CAM ⁺ SAL ⁺ NPL ⁺ <u>P. putida</u> PpG1	RP-1	CAM ⁺ SAL ⁺ NPL ⁺ RP-1 ⁺ <u>P. putida</u> PpG1

The *P. aeruginosa* RP-1 strain is disclosed in the Sykes et al article [Nature 226, 952 (1970)]. Selection for the RP-1 plasmid was accomplished on a neomycin/kanamycin plate. Further, CAM+ SAL+ NPL+ RP-1+ *P. putida* PpG1 has been determined to be resistant to carbenicillin and tetracycline establishing that the RP-1 plasmid is actually present and that the organisms that survived the selection process were not merely the results of mutant development. Also, the plasmids of this superstrain can be transferred and can be cured. The rate of segregation (spontaneous loss) of plasmids from the superstrain has been found to be the same as in the donors.

Both superstrains can, of course, be used as a source of plasmids in addition to those sources disclosed herein. For example, to transfer CAM, SAL or NPL plasmids from CAM+ SAL+ NPL+ RP-1+ *P. putida* PpG1 to a given *Pseudomonas* recipient, the procedures for cell growth of donor and recipient and the mixing thereof for optimized conjugation is the same as described hereinabove. These plasmids will have different frequencies of transfer at different times. The order of diminishing frequency of transfer is CAM, NPL, SAL. For the transfer of CAM plasmid, after conjugation, selection is made for CAM. Surviving colonies are subdivided and selection is made for SAL, NPL and CAM plasmids from each colony. Those protions surviving only on camphor as the sole source of carbon will have received the CAM plasmid free of the SAL or NPL plasmids. The same procedure can be followed for the individual transfer of SAL or NPL plasmids.

In addition to the previously discussed capability for improved treatment of oil spills, considerable improvement is now possible in the microbial single-cell synthesis of proteins from carbon-containing substrates. The restrictions of having to employ substantially single-component substrates, e.g., alkanes, paraffins, carbohydrates, etc. has now been removed, simultaneously providing the opportunity for increases of 50-100 fold in the amount of cell mass that may be produced by a single cell in a given time period, when the given single cell has been provided with multiple energy-generating plasmids. Also, being

able to optimize the protein production of bacteria is of particular interest since bacterial cell mass has a much greater protein content and most bacteria have greater tolerance for heat than yeasts. This latter aspect is of importance since less refrigeration is necessary to remove the heat generated by the oxidative degradation of the substrate.

The general process and apparatus for single cell production of protein is set forth in the Wang article (incorporated by reference) referred to hereinabove. One particular advantage of the multi-plasmid single cell organism of this invention is that after the cell mass has been harvested it can be subjected to a subsequent incubation period in a mineral medium free of any carbon source for a sufficient period of time to insure the metabolism of residual intra-cellular hydrocarbons, e.g. polynuclear aromatics which are frequently carcinogenic. Presently, treatment of cell mass to remove unattacked hydrocarbons often leads to reduction in the quality of the protein product.

The economics of protein production by single-cell organisms will be further improved by the practice of this invention, because of the reduced cost of substrate (e.g. oil refinery residue, waste lubricating oil, crude oil) utilizable by organisms provided with preselected plasmid content.

Cell mass grown in crude oil using NRRL B-5472 was harvested by centrifugation, washed two times in water and dried by blowing air (55°C) over the mass overnight. The dried mass was hydrolyzed and analyzed for amino acid content by the technique described "High Recovery of Tryptophane from Acid Hydrolysis of Proteins" Matsubara et al [Biochem. and Biophys. Res. Comm. 35 No. 2, 175-181 (1969)]. The amino acid analysis showed that the amino acid distribution of superstrain cell mass grown in crude oil is comparable to beef in threonine, valine, cystine, methionine, isoleucine, leucine, phenylalanine and tryptophane content and significantly superior to yeast in methionine content.

Continued capacity for increasing the degrading capability of the superstrains now on deposit has been made

possible by the practice of this invention as more plasmid-borne degradative pathways are discovered. To date *P. aeruginosa* strain 1822 has been provided with all four known hydrocarbon degradative pathways (OCT, CAM, SAL, NPL) plus the drug-resistance factor RP-1 found therein. If there is an upper limit to the number of energy-generating plasmids that will be received and maintained in a single cell, this limit is yet to be reached. Attempts to integrate plasmids (CAM, OCT, SAL) with the cell chromosome have been unsuccessful as indicated by failure to mobilize the chromosome. Such results have so far verified the extrachromosomal nature of the energy-generating and drug-resistance plasmids. There is, of course, no reason to expect that the only plasmids are those that specify degradative pathways for hydrocarbons. Conceivably plasmids may be discovered that will provide requisite enzyme series for the degradation of environmental pollutants such as insecticides, pesticides, plastics and other inert compounds.

Energy-generating plasmids in general are known to have broad inducer and substrate specificity [i.e. enzymes will be formed and will act on a variety of structurally similar compounds]. For example, the CAM plasmid is known to have a very relaxed inducer and substrate specificity [Gunsalus et al—Israel J. Med. Sci., 1, 1099-1119 (1965) and Hartline et al—Journal of Bacteriology, 106, 468-478 (1971)]. Similarly, the OCT plasmid has broad inducer and substrate specificity [Peterson et al—J. Biol. Chem. 242, 4334 (1967)]. In the practice of the instant invention it has been demonstrated that plasmids display the same degree of relaxed specificity in the conjugatant as in the donor.

Thus, by the practice of this invention new facility and capability for growth has been embodied in useful single-cell organisms by the manipulation of phenomena that had been previously undiscovered (i.e. the plasmid-borne nature of the degradative pathways for salicylate and naphthalene) and/or had been previously unsuccessfully applied (i.e., rendering stable a plurality of previously incompatible plasmids in the same single cell).

Filed concurrently herewith is U.S. Application S.N. (RD-5561)—Chakrabarty, filed , 1972 and assigned to the assignee of the instant invention.

What I claim as new and desire to secure by Letters Patent of the United States is:

1. A single cell microorganism containing at least two stable energy-generating plasmids, said plasmids specifying separate degradative pathways.

2. The single cell microorganism of claim 1 wherein the pathways are hydrocarbon degradative pathways.

3. The single cell microorganism of claim 2 wherein the hydrocarbon degradative pathways are selected from the group consisting of linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic.

4. A bacterium containing at least two stable energy-generating plasmids, said plasmids specifying separate degradative pathways.

5. The bacterium of claim 4 wherein the pathways are hydrocarbon degradative pathways.

6. The bacterium of claim 5 wherein the hydrocarbon degradative pathways are selected from the group consisting of linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic.

* * * * *

for Claim 7, see Rejected Claim 7.

* * * * *

For Claims 8 and 9, see Rejected Claims 8 and 9.

10. The *Pseudomonas* bacterium of claim 7 wherein the pathways are hydrocarbon degradative pathways.

11. The *Pseudomonas* bacterium of claim 10, said bacterium being of the specie *P. aeruginosa*.

12. The *Pseudomonas* bacterium of claim 10, said bacterium being of the specie *P. putida*.

* * * * *

For Claim 13, see Rejected Claim 13.

14. The *Pseudomonas* bacterium of claim 13, said bacterium being of the specie *P. aeruginosa*.

* * * * *

For Claim 15, see Rejected Claim 15.

16. The *Pseudomonas* bacterium of claim 13, said bacterium being of the specie *P. putida*.

For Claim 17, see Rejected Claim 17.

18. An inoculum for the degradation of a preselected substrate, said inoculum consisting essentially of single cell microorganisms at least some of which contain at least two stable energy-generating plasmids, said plasmids specifying separate degradative pathways.

19. The inoculum of claim 18 wherein the degradative pathways in the microorganisms having multiple energy-generating plasmids are hydrocarbon degradative pathways.

20. The inoculum of claim 19 wherein the hydrocarbon degradative pathways are selected from the group consisting of linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic.

* * * * *

For Claim 21, see Rejected Claim 21.

22. The inoculum of claim 21 wherein the degradative pathways in the bacteria having multiple energy-generating plasmids are hydrocarbon degradative pathways.

23. The inoculum of claim 21 wherein the bacteria having multiple energy-generating plasmids are of the genus *Pseudomonas*.

* * * * *

For Claims 24 to 26 inclusive, see Rejected Claims 24 to 26 inclusive.

27. In the process in which a first energy-generating plasmid specifying a degradative pathway is transferred by conjugation from a donor single cell organism to a recipient single cell organism containing at least one energy-generating plasmid that is incompatible with said first plasmid, said transfer occurring in the quiescent state after the mixing of substantially equal volumes of cultures of said donor and said recipient, each culture presenting the respective organisms in a complex nutrient liquid medium at a population density of at least about 1,000,000 cells/ml, the improvement wherein after conjugation has occurred, the multi-plasmid conjugant

organisms are subjected to DNA-cleaving radiation in a dosage sufficient to fuse the first plasmid and the plasmid incompatible therewith located in the same cell.

* * * *

For Claim 28, see Allowed Claim 28.

29. The improvement of claim 28 wherein the single cell organisms are of the genus *Pseudomonas*, the first plasmid specifying the degradative pathway for camphor and the recipient *Pseudomonas* containing the degradative pathway for n-octane.

30. An inoculated medium for the degradation of floating liquid hydrocarbon substrate material, said inoculated medium comprising a buoyant carrier material and single cell microorganisms carried thereby, at least some of said microorganisms containing at least two stable energy-generating plasmids specifying separate hydrocarbon degradative pathways and said carrier material being able to absorb said hydrocarbon material.

* * * *

For Claims 31 and 32, see Allowed Claims 31 and 32.

33. The inoculated medium of claim 32 wherein the multiplasmid containing single cell microorganisms are bacteria.

34. The inoculated medium of claim 33 wherein the bacteria are of the genus *Pseudomonas*.

35. The inoculated medium of claim 34 wherein the bacteria are of the specie *P. aeruginosa*.

36. The inoculated medium of claim 34 wherein the bacteria are of the specie *P. putida*.

DECLARATION, POWER OF ATTORNEY, AND PETITION

I, Ananda M. Chakrabarty declare that I am a citizen of India residing at Latham, New York; that I have read the foregoing specification and claims and I verily believe I am the original, first, and sole inventor of the invention in Microorganisms Having Multiple Compatible Degradative Energy-Generating Plasmids and Prepara-

tion Thereof described and claimed therein; that I do not know and do not believe that this invention was ever known or used before my invention thereof, or patented or described in any printed publication in any country before my invention thereof, or more than one year prior to this application; or in public use or on sale in the United States more than one year prior to the application; that this invention has not been patented in any country foreign to the United States on an application filed by me or my legal representatives or assigns more than twelve months before this application; and that no application for patent on this invention has been filed by me or my representatives or assigns in any country foreign to the United States, except as follows:

And I hereby appoint John F. Ahern, Charles T. Watts and Leo I. MaLossi, Corporate Research and Development, Bldg. K-1, General Electric Company, P.O. Box 8, Schenectady, New York 12301, and Frank L. Neuhauser, Reg. No. 14975, Oscar B. Waddell, Reg. No. 15415, and Joseph B. Forman, Reg. No. 15795, Washington Patent Operation, General Electric Company, 2001 Jefferson Davis Highway, Arlington, Virginia 22202, jointly, and each of them severally, my attorneys and attorney, with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent and to transact all business in the Patent Office connected therewith. I hereby direct that all correspondence in connection with this application be addressed to the said John F. Ahern, Corporate Research and Development, Building K-1, General Electric Company, P.O. Box 8, Schenectady, New York 12301.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false

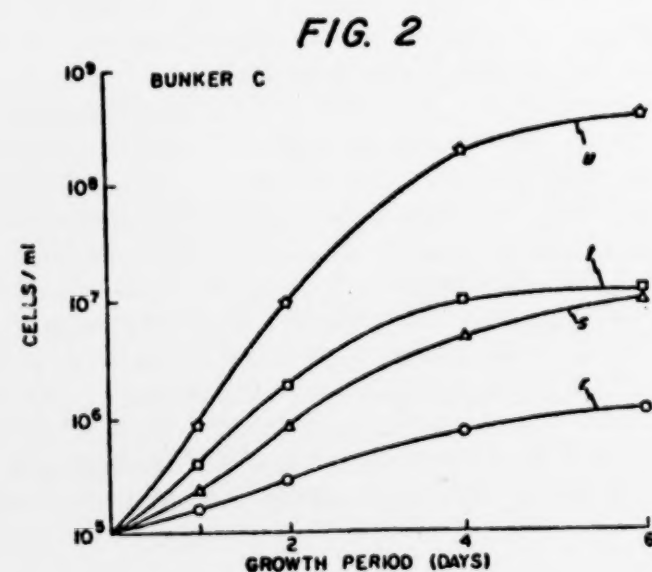
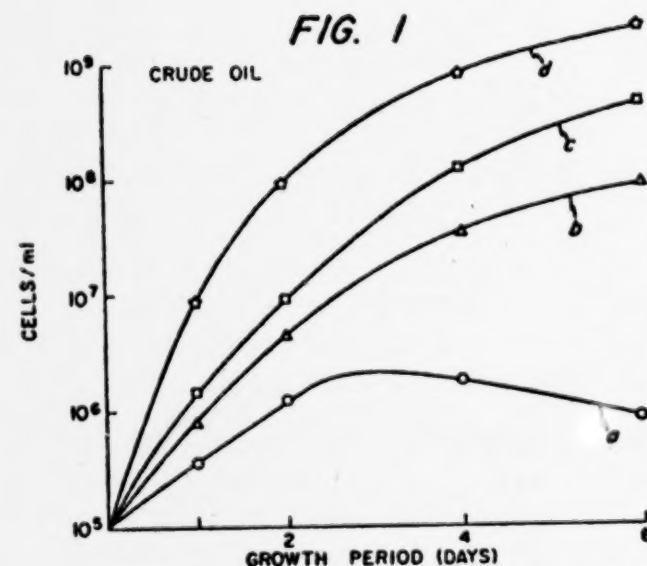
statements may jeopardize the validity of the application or any patent issuing thereon.

Wherefore I pray that Letters Patent be granted to me for the invention described and claimed in the foregoing specifications and claims, and I hereby subscribe my name to the foregoing specification and claims, declaration, power of attorney, and this petition, this 1 day of June, 1972.

Inventor ANANDA M. CHAKRABARTY
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PRINT OF DRAWINGS
 AS ORIGINALLY FILED

260563



AMENDMENT, DECEMBER 6, 1973

3

Honorable Commissioner of Patents,

SIR:

In response to the Office Action dated September 19, 1973, please amend the above-identified application as follows:

Page 1, line 16, delete "Transmissible" and
insert—Transmissible—

Page 25, line 13, delete "suggests" and insert —suggest—
Cancel claims 1-6, 10-12, 14, 16, 18-20, 22, 23 and 33.

For Claim 7, see Rejected Claim 7.

For Claim 21, see Rejected Claim 21.

Claim 34, line 1, delete "33" and insert —30—

REMARKS

The rejection of claims 7-9, 13, 15, 17, 21, 24-32 and 34-36 in the Office Action dated September 19, 1973 is respectfully traversed. Withdrawal of the grounds of rejection set forth therein is respectfully requested.

With respect to the rejection of claims 1-26 under 35 U.S.C. 101 as being nonstatutory, attention is respectfully directed to Section 706.03(a) Nonstatutory Subject Matter. In the example of "Naturally Occurring Article" the statement is made that "a thing occurring in nature, *which is substantially unaltered*, is not a 'manufacture'" (emphasis supplied). The organisms disclosed and claimed by Applicant are not different in *degree* from the natural characteristics of such organisms, but are different in *kind*, the natural organism having been made into one having a totally new capability.

Thus, in the case of spills of crude oil, it is important that the oil spill be degraded quickly with coalesce of the remaining portions into large drops whereby the oppor-

tunity for spreading of the oil over the water is obviated. As is explained in applicant's specification, page 11, line 6, through page 12, line 20, a mixed culture does not have the equivalent capability of a single organism having multiple degradative pathways.

As is pointed out in the Handbook of Patents by H. A. Toulmin, Jr. (The W. H. Anderson Company, 1948, page 40), "A patentable composition of matter may well result or be formed by the intermixture of two or more ingredients, which develop a different or additional property or properties which the several ingredients individually do not possess in common". On this same page in the Toulmin text appears a quotation from Commercial Acetylene Co. v. Avery Portable Lighting Co. 166 Fed. 907, "There is no restriction as to the nature of the composition which may be patented. The only limitation is they must be new, useful and the result of invention." Thus, it is respectfully submitted that these new *Pseudomonas* bacteria may be considered compositions of matter. On the other hand, in the text Patent Claims by Ridsdale Ellis (Baker, Voorhis & Co., Inc., 1949, page 436) it is pointed out that the authors of the patent statutes intended "manufacture" to mean anything "made" other than those articles which fall within the classes of machines on the one hand and compositions of matter on the other.

It is respectfully submitted that whether the *Pseudomonas* bacteria claimed in Applicant's specification are considered compositions of matter or manufacturers, they clearly are new and different organisms having distinctive capabilities, character and use. In Funk Bros. Seed Co. v. Kalo Inoculant Co., 76 USPQ 280 in the carryover paragraph, page 281 to 282, it is pointed out that "The combination of species produces *no new bacteria*, *no change* in the six species of bacteria, and *no enlargement* of the range of their *utility*. Each species has the same effect it always had." (emphasis supplied). Thus, presumably, had the patentee produced new, changed bacteria with an enlarged range of utility (as is the case in the instant application), the Court would have been able to conclude that the product claims fully met the statutory requirements.

It is respectfully submitted that the claims 27-32 and 34-36 as amended fully comply with the requirements of 35 U.S.C. 112. Specifically, with respect to claims 27 (couched in Jepson form) in which the term "complex nutrient liquid medium" is recited in the introductory portion thereof, since several such liquid nutrient media may be used, it is respectfully submitted that this aspect of the invention is not critical and, as a result, more generally terminology should be permitted.

With respect to the rejection of claims 1, 4, 18 and 21 under 35 U.S.C. 103 as unpatentable over the Annual Review article, this reference has been examined and, it is respectfully submitted, that none of the plasmids replicated include *energy-generating plasmids* of any sort.

Claim 30 has been rejected under 35 U.S.C. 103 as unpatentable over the Annual Review article. This ground of rejection is respectfully traversed for the reason set forth hereinabove.

Thus, it is respectfully submitted that claims 7-9, 13, 15, 17, 21, 24-32 and 34-36 fully comply with all statutory requirements and patentably define over the reference cited. Allowance of these claims and passage of the case to issue are respectfully requested.

In the event the Examiner in charge of this application desires to initiate a telephone interview, the undersigned may be reached at the following number.

Area Code 518
346-8771, Ext. 6514.

Respectfully submitted,

LEO I. MALOSSİ
Leo I. MaLossi, Attorney
Reg. No. 18,990

AMENDMENT, APRIL 8, 1974

Honorable Commissioner of Patents,

SIR:

In response to the Final Rejection dated January 11, 1974, please amend the above-identified application as follows in accordance with the provisions of Rule 116:

Page 30, line 20, delete "source" and insert —source—

Page 42, line 21, delete "(RD-5561)" and insert —260,-488—; after "filed" insert —June 7—

For Claim 30, see Allowed Claim 30.

* * * * *

REMARKS

The Final Rejection of claims 7-9, 13, 15, 17, 21, 24-26 and 30-32 is respectfully traversed. Withdrawal of the grounds of rejection set forth therein is respectfully requested. The allowance of claims 27-29, the indication of the allowability of claims 34-36 and the statement that claims 30-32 are free of the prior art are respectfully noted.

With respect to the rejection of claims 7-9, 13, 15, 17, 21 and 24-26 under 35 U.S.C. 101 as not being within the statutory classes, this ground of rejection is respectfully traversed. It is respectfully submitted that Applicant has presented claims to a patentable composition of matter or, in the alternative to a manufacture, both of which constitute statutory classifications provided for by 35 U.S.C. 101.

As is clearly stated in *Merck & Co., Inc. v. Olin Mathieson Chemical Corp.*, 116 USPQ 484, 488 "There is nothing in the language of the Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability. All of the tangible things with which man deals and for

which patent protection is granted are products of nature in the sense that nature provides the basic source materials. The 'matter' of which patentable new and useful compositions are composed necessarily includes naturally existing elements and materials."

The court in *Riter-Conley Mfg. Co. v. Aiken et al*, 203 Fed. 699, 703 in quoting from an earlier case, states that "the term 'manufacture' as used in the patent law, has a very comprehensive sense, embracing whatever is made by the art or industry of man, not being a machine, a composition of matter, or a design,". Also, additional discussion of the term "manufacture" on page 701 of this case points out that "From its original derivation of 'facere manu', or handworked products, the word has broadened into all means of treating raw materials . . ." (underlining added).

It is respectfully submitted that in view of such statements by the courts, Applicant's claims fall into one or the other (or both) statutory class of "composition" and "manufacture". It is further respectfully submitted that, since Applicant's invention has been fully, clearly, concisely and exactly described in Applicant's specification, the invention is claimable as a new and unobvious composition or, at the least, as a new and unobvious manufacture. And, further, these claims merit patenting, because no evidence has been produced that the organisms claimed a) existed before, either naturally or by deliberate construction or b) have been specifically suggested in the art together with directions for their preparation.

The accompanying Declaration Under Rule 132 by Dr. Ananda M. Chakrabarty is presented to clarify the nature of the change that occurs in the parent microorganism, when a degradative plasmid has been introduced thereinto. As is pointed out in the Declaration, a cooperative activity ensues between the plasmid and the parent microorganism, once compatibility has been established. As a result, the genetically engineered organism achieves a capability for degrading various crude oil components not present in the parent cell and, thereafter, as replication occurs, all of the genetic information passes on to

future strains. Thus, it is respectfully submitted that a *fundamental* alteration has occurred in the parental cell so that it is erroneous to conclude that the genetically engineered organism is "a thing occurring in nature that is substantially unaltered".

The Supreme Court of the United States in *Funk Bros. Seed Co. v. Kalo Inoculant Co.* 333 US 127, 68 SC 440, 76 USPQ 280 sets forth clear and distinct rules by which it may be recognized whether the qualities of the bacterium set forth in a patent claim are merely "the work of nature" or whether some law or nature has actually been applied to a new and useful end (76 USPQ 281, column 2—p282, column 1). Thus, it appears that in order to establish that some law of nature has been applied to a new and useful end, the Court would expect to see that:

- a) a new bacterium has been produced.
- b) a change in the bacterium has been brought about or
- c) an enlargement in the range of the utility of the bacterium has resulted.

It is respectfully submitted that in the instant application, Applicant has adequately met this test having produced genetically engineered organisms, that are very markedly changed from the parent cells, which parent cells after alteration embody (and will reproduce) in a single organism capabilities never found to exist in a single organism before.

Thus, it is respectfully submitted that the guidelines provided by the Supreme Court together with the information provided in the enclosed Declaration much more adequately deal with the questions of the patentability of Applicant's claims than such case law as *Ex parte Grayson* 51 USPQ 413 (shrimp), *American Food Growers, Inc. v. Brogdex Company* 8 USPQ 131 (orange) or *Hartranft v. Wiegmann* 121 USPQ 609 (shells), none of which relate to bacteria and, more importantly, none of which involve a fundamental alteration of the natural article.

The rejection of claims 30-32 under 35 U.S.C. 112 is respectfully traversed. Claim 30 (and thereby claims 31 and 32) has been amended to specifically recite *Pseudomonas*.

Thus, it is respectfully submitted that claims 7-9, 13, 15, 17, 21, 24-26 and 30-32 (together with allowed and allowable claims 27-29 and 34-36) fully comply with the statutory requirements for patentability. Allowance of all claims and passage of the case to issue are respectfully requested.

In the event the Examiner in charge of this application cannot agree as to the patentability of these claims, entry of this amendment (and Declaration) for purposes of appeal is respectfully requested.

In the event the Examiner in charge of this application desires to initiate a telephone interview, the undersigned may be reached at the following number:

Respectfully submitted,

LEO I. MALOSSI
Leo I. MaLossi, Attorney
Reg. No. 18,990

April 5, 1974

DECLARATION OF CHAKRABARTY

I, Ananda M. Chakrabarty, of the General Electric Company Research and Development Center, Schenectady, New York, declare that:

1. After receiving the degree of Doctor of Philosophy in biochemistry from Calcutta University in 1965, I joined the University of Illinois (Urbana, Illinois) as a Post Doctoral Research Associate. Since leaving the University of Illinois in 1971, I have been employed as a Staff Microbiologist by the General Electric Company at the Research and Development Center (R&DC). Both during my post doctoral work and while on the staff at the R&DC, I have been engaged in investigations in viral transmission of genetic materials in microorganisms and in the construction of genetically engineered microorganisms for the production of useful materials.

2. In connection with my research efforts, I have been the author or co-author of approximately 25 technical papers in the above areas of investigation.

3. I am the inventor in the above-identified application and wish to comment on the extent to which the *Pseudomonas* bacterium claimed (hereinafter referred to as "genetically engineered organism" or "GEO") therein is different from the parental cell organism (PC).

The GEO has been constructed as a genetically improved strain by transferring to the PC genetic materials from other microorganism(s), each of which has the capability for degrading a different component of crude oil. The genetic materials are transferred in the form of plasmids, which become physically incorporated into the cellular structure of the PC. The genetic materials so introduced are either naturally compatible with any other plasmid in the PC or are deliberately rendered compatible by fusion. Thereafter, these genetic materials become stably inheritable.

Once stabilized, not only is the plasmid-supplied genetic material tolerated by the PC, but a mutual cooperation results. Thus, at the direction of the plasmid, the PC operates its protein-generating machinery to produce

hydrocarbon-degrading enzymes, which are completely new within the cellular environment of the PC. This provides to the PC a new capability for degrading one or more crude oil components depending upon the number of plasmids transferred. Thereafter, as the PC replicates, all this genetic information passes on to the daughter strains for an indefinite number of generations.

Thus, I have not simply brought about a mutational change of the genetic material but have brought to the PC substantial quantities of new genetic material (as much as 25% more DNA) from different microorganisms resulting in altered composition of the cellular material of the PC. The fact that this is a *fundamental* alteration is evidenced by the relative survival capabilities of the GEO and the PC in crude oil and in Bunker C. These growth capabilities are described in the specification of the above-identified application (page 29, line 17—page 34, line 8) and in the drawing thereof.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

April 5, 1974

Date

ANANDA M. CHAKRABARTY
Ananda M. Chakrabarty

REJECTED CLAIMS

7. A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

8. The *Pseudomonas* bacterium of claim 7, said bacterium being of the specie *P. aeruginosa*.

9. The *Pseudomonas* bacterium of claim 7, said bacterium being of the specie *P. putida*.

13. The *Pseudomonas* bacterium of claim 7 wherein the hydrocarbon degradative pathways are selected from the group consisting of linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic.

15. The *P. aeruginosa* bacterium of claim 8 wherein the bacterium contains CAM, OCT, SAL, and NPL plasmids.

17. The *P. putida* bacterium of claim 9 wherein the bacterium contains CAM, SAL, NPL and RP-1 plasmids.

21. An inoculum for the degradation of a pre-selected substrate comprising a complex or mixture of hydrocarbons, said inoculum consisting essentially of bacteria of the genus *Pseudomonas* at least some of which contain at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

24. The inoculum of claim 21 wherein the hydrocarbon degradative pathways are selected from the group consisting of linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic.

25. The inoculum of claim 24 wherein the bacteria having multiple energy-generating plasmids are of the specie *P. aeruginosa*.

26. The inoculum of claim 24 wherein the bacteria having multiple energy-generating plasmids are of the specie *P. putida*.

ALLOWED CLAIMS

27. In the process in which a first energy-generating plasmid specifying a degradative pathway is transferred by conjugation from a donor *Pseudomonas* bacterium to a recipient *Pseudomonas* bacterium containing at least one energy-generating plasmid that is incompatible with said

first plasmid, said transfer occurring in the quiescent state after the mixing of substantially equal volumes of cultures of said donor and said recipient, each culture presenting the respective organisms in a complex nutrient liquid medium at a population density of at least about 1,000,000 cells/ml, the improvement wherein after conjugation has occurred, the multi-plasmid conjugatant bacteria are subjected to DNA-cleaving radiation in a dosage sufficient to fuse the first plasmid and the plasmid incompatible therewith located in the same cell.

28. The improvement of claim 27 wherein the DNA-cleaving radiation is UV radiation.

29. The improvement of claim 28 wherein the first plasmid provides the degradative pathway for camphor and the recipient *Pseudomonas* contains the degradative pathway for n-octane.

30. An inoculated medium for the degradation of liquid hydrocarbon substrate material floating on water, said inoculated medium comprising a carrier material able to float on water and bacteria from the genus *Pseudomonas* carried thereby, at least some of said bacteria each containing at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway and said carrier material being able to absorb said hydrocarbon material.

31. The inoculated medium of claim 30 wherein the carrier material is straw.

32. The inoculated medium of claim 30 wherein the hydrocarbon degradative pathways are selected from the group consisting of linear aliphatic, cyclic aliphatic, aromatic and polynuclear aromatic.

35. The inoculated medium of claim 30 wherein the bacteria are of the specie *P. aeruginosa*.

36. The inoculated medium of claim 30 wherein the bacteria are of the specie *P. putida*.

Filed
U.S. Court of Customs
and Patent Appeals
Dec 28 '76
George E. Hutchinson
Clerk

PETITION OF APPEAL

To the United States Court of Customs
and Patent Appeals:

Your Petitioner, Ananda M. Chakrabarty, of Latham, New York, respectfully represents:

That he is the original and first inventor of a certain new and useful bacterium from the genus *Pseudomonas*.

That on June 7, 1972, in the manner prescribed by law, he presented his application to the Patent and Trademark Office praying that a patent be issued to him for said invention.

That proceedings were had in said Office upon said application; that on May 20, 1976, and October 19, 1976, said application was rejected by the Board of Appeals and a patent for said invention as set forth in claims 7, 8, 9, 13, 15, 17, 21, 24, 25 and 26 of said application was refused him.

That on November 18, 1976, your Petitioner pursuant to Section 142 of Title 35, United States Code, gave notice to the Commissioner of Patents of his appeal to this Honorable Court from his refusal to issue a patent to him for the invention set forth in said claims and filing with him in writing the special reasons of appeal.

That the Commissioner of Patents has furnished him a certified transcript of the record and proceedings relating to said application for patent including the Notice and Reasons of Appeal, which transcript is filed herewith together with a check for fifty dollars (\$50.00) for the filing fee.

Wherefore, your Petitioner prays that his appeal may be heard upon and, for the reasons assigned therefor to

the Commissioner, that the decision of the Commissioner be reversed.

Respectfully submitted,

ANANDA M. CHAKRABARTY,
By his attorney,
Leo I. MaLossi JBF
LEO I. MALOSI
P.O. Box 8
Schenectady, New York 12309

December 27, 1976

Of Counsel

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UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Appeal No. 77-535
Serial No. 260,563

IN THE MATTER OF THE APPLICATION OF
ANANDA M. CHAKRABARTY

ORDER

The Supreme Court of the United States having vacated the judgment in *Parker v. Bergy, et al.* on June 22, 1978, and remanded that case for further consideration in light of *Parker v. Flook*, decided by the Supreme Court on June 22, 1978; and the Commissioner of Patents and Trademarks having petitioned to vacate the judgment and recall the mandate in this appeal in view of that action of the Supreme Court;

IT IS ORDERED

That the petition is granted to the extent that the judgment in this appeal is vacated, the mandate in this appeal is recalled and this appeal is restored to the calendar.

IT IS FURTHER ORDERED

That the parties shall file supplementary briefs directed solely to the effect of *Parker v. Flook* on this appeal. Briefs shall be filed in accordance with the following schedule:

Appellant's Brief—40 days after date of this order
Commissioner's Brief—70 days after date of this order

Reply Brief—84 days after date of this order

The case will be set for hearing on November 6, 1978.

FOR THE COURT

/s/ Howard T. Markey
HOWARD T. MARKEY
Chief Judge

Dated: 11 Aug. 78

SUPREME COURT OF THE UNITED STATES

No. 79-136

LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS, PETITIONER

v.

MALCOLM E. BERGY, ET AL.; and

LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS, PETITIONER

v.

ANANDA M. CHAKRABARTY

ORDER ALLOWING CERTIORARI

Filed October 29, 1979

The petition herein for a writ of certiorari to the
United States Court of Customs and Patent Appeals is
granted.

SEP 24 1979

IN THE
Supreme Court of the United States
OCTOBER TERM, 1978

No. 79-136

LUTRELLE F. PARKER, ACTING COMMISSIONER OF
PATENTS AND TRADEMARKS, *Petitioner*

v.

MALCOLM E. BERGY, ET AL

LUTRELLE F. PARKER, ACTING COMMISSIONER OF
PATENTS AND TRADEMARKS, *Petitioner*

v.

ANANDA M. CHAKRABARTY

**CHAKRABARTY'S BRIEF IN OPPOSITION TO
PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF
CUSTOMS AND PATENT APPEALS**

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1978

—
No. 79-136
—

LUTRELLE F. PARKER, ACTING COMMISSIONER OF
PATENTS AND TRADEMARKS, *Petitioner*

v.

MALCOLM E. BERGY, ET AL

—
LUTRELLE F. PARKER, ACTING COMMISSIONER OF
PATENTS AND TRADEMARKS, *Petitioner*

v.

ANANDA M. CHAKRABARTY

—
**CHAKRABARTY'S BRIEF IN OPPOSITION TO
PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF
CUSTOMS AND PATENT APPEALS**
—

Respondent, Ananda M. Chakrabarty, opposes the petition for writ of certiorari to the United States Court of Customs and Patent Appeals.

QUESTION PRESENTED

Whether patent claims to a concededly novel and unobvious microorganism, useful in treatment of oil spills, should be denied, solely because the microorganism is alive.

STATEMENT OF THE CASE

Chakrabarty's invention is in the relatively new and highly complex field of cellular or genetic engineering or microbial genetics. His microorganism is a bacterium engineered to solve one of man's practical needs, getting rid of oil spills. The bacterium breaks down or degrades components of the oil into simpler substances which serve as its food. Ultimately the bacterium becomes food for aquatic life. Thereby the oil is absorbed into the sea on which it floats.

Oil is a mixture of several component hydrocarbon compounds, and the ability to break down one component is not the ability to break down others. Various bacteria are known to degrade various components of oil, but, unfortunately, any given strain of bacteria can degrade only a particular component. Prior biological control of oil spills therefore involved use of a mixture of bacterial strains, each capable of degrading a different component of the oil. However, because of other characteristics of these bacterial strains, only a portion of them survive to attack the oil components. Thereby, when a mixture of bacteria cultures is deposited on an oil spill, the bulk of the oil often remains unattacked for a long period of time and is free to spread or sink.

Chakrabarty constructed a new microorganism having the capacity of degrading several different com-

ponents of oil. Thereby, the problems resultant from the prior need for a mixture of a number of different strains were avoided. Oil degradation with Chakrabarty's man-made bacterium occurs more rapidly. This new bacterium is significantly different from naturally occurring microorganisms, with a markedly greater range of utility.

Claims to an improvement in oil degradation by use of Chakrabarty's bacterium have been allowed (Patent No. 3,813,316¹). Claims to a floatable carrier (straw is preferred) inoculated with the bacterium have also been allowed in the application involved in this case. Accordingly, whatever the ultimate disposition of the claims involved in this petition, patent protection for Chakrabarty's invention has and will issue.

However, claims to the bacterium, itself, were rejected by the Examiner. These claims concededly define subject matter which is properly disclosed and is both novel and unobvious. Rejection was because the subject matter assertedly was not within the categories of invention enumerated in 35 U.S.C. 101. The rejected

¹ Claim 1 of that patent is as follows:

"In the process of microbial degradation of a substrate as a carbon source wherein a culture of microorganisms is brought into contact with a primary substrate comprising a complex or mixture of hydrocarbons in the presence of requisite mineral salts at temperatures favorable to growth of said microorganisms, the improvement of employing a bacterial culture that includes at least one *Pseudomonas* bacterium containing at least two stable energy-generating plasmids therein, said plasmids providing separate hydrocarbon degradative pathways by each of which a sequence of enzymatic reactions is made available to convert said primary substrate to simple common metabolites."

claims were said to be for "a thing occurring in nature" (App. H165a-167a²).

The Board of Appeals of the Patent and Trademark Office reversed the Examiner's holding that the claims are for "products of nature". The Board's reason was that the claimed bacterium does not in fact occur naturally. However, the rejected claims were held not to be within 35 U.S.C. 101, because they are "drawn to live organisms" (App. G159a-164a).

The Court of Customs and Patent Appeals reversed, holding that claims to a bacterium are not excluded from 35 U.S.C. 101 because it is alive. *In Re Chakrabarty*, 571 F.2d 40 (CCPA 1978) (App. F142a-148a). That Court's earlier holding in *In Re Bergy*, 563 F.2d 1031 (1977) (App. C106a-121a) was stated to be controlling. (*Bergy* involves a naturally occurring microorganism which is isolated and purified to a form not occurring in nature. The bacterium of *Chakrabarty*, however, does not occur naturally, in any form. It is made by man.)

This Court granted certiorari in *Bergy*, vacated the ruling of the Court of Customs and Patent Appeals therein and remanded for further consideration in light of *Parker v. Flook*, 437 U.S. 584 (1978). This Court did not consider the petition for certiorari in *Chakrabarty*. Rather, the petition was dismissed by stipulation after the Court below vacated its ruling, for reconsideration together with *Bergy*.

After briefing and argument of the significance of *Flook*, the Court of Customs and Patent Appeals re-

² References here (and in the Petition) to appendices are to the appendices to the Petition, where are reproduced the various opinions associated with this case.

affirmed its earlier judgments in both cases (App. A 1a-70a), holding that the living character of *Chakrabarty*'s bacterium and *Bergy*'s microorganism does not disqualify them from patent protection under 35 U.S.C. 101. (One of the two dissenters to the earlier judgment, Judge Baldwin, changed his dissent to a concurring opinion, expressly based on the *Flook* opinion. App. A 71a-94a.)

Petition for certiorari in both cases was filed on July 27, 1979. Extension of time to September 29, 1979, was granted, and this opposing brief is filed within that extended time.

REASONS FOR DENYING THE WRIT

The question presented by this petition, as to *Chakrabarty*, is not properly the question propounded by petitioner concerning patentability of life, itself. *Chakrabarty* claims a man-made bacterium, not life in general. Properly speaking, the question is whether claims to *Chakrabarty*'s bacterium should be denied solely because it is alive. That question has been decided in respondent's favor by the Court below.

Petitioner claims that this Court's decision in *Parker v. Flook*, 437 U.S. 584 (1978) requires a different result than reached by the Court below. As will be shown, the Court below fully considered the applicability of both the holding and the rationale of *Parker v. Flook* in reaching its conclusion.

Petitioner also claims that, in adopting the patent law, the 1874 Congress did not intend that living things be protected by patents. Petitioner relies on adoption by different, later, Congresses of the Plant Patent Act of 1930, and the Plant Variety Protection Act of 1970.

The Court below also fully considered these Acts and their application to determination of Congressional intent in adoption of what is now 35 U.S.C. 101.

There is no sufficient reason for a further layer of judicial consideration of these arguments.

1. Contrary to the petition's assertion, the Court below did not reject this Court's opinion in *Parker v. Flook*, 437 U.S. 584 (1978). In a thorough opinion, the Court carefully considered *Flook* and its application to *Chakrabarty*, but decided that neither this Court's holding nor its opinion in *Flook* required rejection of the claims here involved.

Flook held that the method of calculation of alarm limits there involved was not patentable subject matter under 35 U.S.C. 101. That *holding* has no bearing on whether the microorganisms here involved are patentable subject matter under that section, as the Court below noted (App. A 22a).

In *Flook* this Court also likened the mathematical algorithm of that case to a law of nature, which could not be withdrawn from the public by patent protection, even if it were first discovered by the applicant for such protection. But this comparison also has no application to *Chakrabarty*, where there is nothing like a law of nature to be withdrawn from the public; rather, there is only a new man-made bacterium that never *existed* before *Chakrabarty's* invention.³ Again, *Flook* does not require a different result in this case.

³ Petitioner's suggestion as to the economic implications and the vastness of the technological area affected by this decision evidently ignores the admission at the end of the same petition that patent protection is properly granted for processes using live microorganisms. The incremental economic impact of allowance of claims to microorganisms themselves, as distinguished from claims to their

The Court below also expressed regret at this Court's method of analysis of the claims in *Flook*, by which the mathematical algorithm was treated as a "familiar part of the prior art", and patentability of the claimed process analyzed with its only assertedly novel element treated as old. Whatever the impact of that analysis on other cases, it has none here, where there is nothing like a mathematical algorithm or a law of nature to be treated as old. There is rather a new man-made microorganism (App. A 22a-24a).

Finally, the Court below recognized that in *Flook*, this Court repeated its warning in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972):

"[W]e should not expand rights by overruling or modifying our prior cases construing the patent statutes unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language. We would require a clear and certain signal from Congress before approving the position of a litigant who, as respondent here, argues that the beachhead of privilege is wider and the area of public use narrower, than the courts had previously thought. No such signal legitimizes respondent's position in this litigation."

uses, is not suggested. However, in this age of need for new technology to solve mankind's problems, including oil spills, it ill behooves the government to suggest eliminating the patent incentive from a significant technological area, whether or not it is vast.

Petitioner's suggestions of the difficulty in determining whether infringement exists and of the complication to government policy concerning desirability of recombinant DNA research similarly are without merit. The former is unsupported, even by the authorities cited; the latter has nothing to do with the matter here presented. Indeed, *Chakrabarty's* microorganism does not involve recombinant DNA. Whether or not research should be conducted in that field will not be affected in any way by this case.

That language quoted in *Flook* from *Deepsouth* is not applicable here both because there is no expansion and there is no precedent overruled or modified by the decision of the Court below. *Deepsouth* involved expansion of patent protection to cover the sale of un-assembled parts which were first assembled abroad, contrary to prior decisions. *Flook* involved expansion of patent protection to cover a conventional method for updating alarm limits, wherein the only novelty was in an unprotectable mathematical algorithm. That extension would have been contrary to a prior decision of this Court foreclosing protection of mathematical algorithms.

As the Court below noted, patent claims have previously been granted for living things (App. A 65a-67a). There is no *expansion* here; there is rather an attempted *restriction* in the scope of the patent laws by the Patent and Trademark Office (PTO). The PTO seeks to have this Court add to 35 U.S.C. 101 a requirement not stated therein, namely that the invention not be alive. That would be improperly limiting the expression of the Congress. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933), quoted by the Court below (App. A 70a).

In *Chakrabarty*, moreover, there are no overruled or modified precedents. These are issues of first impression, the only known cases in which an otherwise patentable article has been argued to be foreclosed patent protection because it is alive (App. A 21a, 25a).

The petition asserts that "*dicta*" in earlier cases "suggest that living things are not patentable". *Guaranty Trust Co. v. Union Solvents Corp.*, 54 F.2d 400, 410 (D. Del. 1931) *aff'd.* on lower court's opinion, 61

F.2d 1041 (3rd Cir. 1932), cert. denied 288 U.S. 614 (1933), concerned a fermentation process employing newly found and isolated bacteria. In holding the patent on the process *valid* the District Court stated:

"... the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the life process of a living organism. Were the patent for bacteria *per se*, a different situation would be presented."

Admittedly *dicta*, this is not even a statement that claims to the bacteria *per se* would *not* be patentable; nor that their *living nature* would be the reason for unpatentability. If the bacteria were found in nature, they may not have been novel and have been unpatentable for that reason.

Application of Mancy, 499 F.2d 1289, 1294 (CCPA 1974) concerned a process of use of a bacterium found in nature. The Court of Customs and Patent Appeals assumed, expressly without deciding, that claims to the bacterium *per se* would be unpatentable. The reason given was that it was a "product of nature", *not* that it was alive.

By citing *Mancy* as a precedent, petitioner confuses the "living thing" rejection, new with these cases, with the well-known "product of nature" rejection⁴ which led to the Plant Patent Act, shortly to be discussed. Of course, a "product of nature" is not necessarily a living thing. Nature produces many things which are not alive, e.g., metals, fuel such as coal and oil, gems,

⁴ Called "naturally occurring article", this rejection is expressly mentioned in The Patent and Trademark Office Manual of Patent Examining Procedure, § 706.03(a). No such mention occurs for the new "living thing" rejection.

etc. A "living thing" is also not necessarily a product of nature, just as the Chakrabarty bacterium concededly is not, but rather is man-made.

Not only are the cited statements in *Mancy* and *Guaranty Trust* admitted dicta, but they are not even precedents for the "living thing" rejection here. There is no controlling precedent overruled or modified by the decision below. The caution expressed in *Deepsouth* and *Flook* is not applicable here.⁵

Clearly the Court below fully considered *Parker v. Flook*. Petitioner seeks to have this Court expend further judicial time on the very same matter.

2. The petition asserts that the Congress which enacted the 1874 predecessor to 35 U.S.C. 101 did not intend to include living things within that statute, because the Congress serving in 1930 and the Congress serving in 1970 enacted special statutes protecting plant inventions. As the Court below pointed out, this argument improperly seeks to infer the intent of one Congress from acts of later Congresses (App. A 51a-52a). Moreover, the petition depends on the syllogism

1) plants are living things;

2) plants were not patentable before the 1930 Plant Patent Act, 35 U.S.C. 161 *et seq.* and therefore,

⁵ This Court previously considered patentability of bacteria in *Funk Bros. Co. v. Kalo Co.*, 333 U.S. 127 (1947). The live condition of the bacteria was not stated to foreclose patentability. Rather, unlike *Chakrabarty's* new man-made bacterium, the patented mixture in *Funk* was of a number of old, naturally-occurring bacteria. The patentee in *Funk* had discovered that certain strains of different species of bacteria were compatible. He obtained a patent on a mixture of compatible strains. The Court held that this amounted to discovery of a law of nature and was unpatentable.

3) living things were not patentable before the 1930 Plant Patent Act.

The obvious question is whether it was their *living nature* which excluded plants from patent protection before 1930. The petition's only asserted support for its affirmative answer is a portion of a letter from the Secretary of Agriculture, not shown to have any expertise in the patent law, that only inventions or discoveries in the field of "inanimate nature" are "understood" to be within the patent law. H. R. Rep. No. 1129, 71st Cong., 2d Sess. 10 (Appendix A) (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 9 (Appendix A) (1930). That understanding is not only unclear; it is not shown to have had any impact on the Congress.

The Court below had much more documented answers, based on the expressed purposes of the House and Senate Reports on the Plant Patent Act, and the then long-standing rejection of claims to "products of nature". As the Court below noted (App. A 59a-60a), the Commissioner of Patents as long ago as 1889 had expressed the "product of nature" rejection of claims to a naturally occurring material (i.e., a fiber taken from a tree). *Ex Parte Latimer*, 1889 Commissioner's Decisions 123, 460 Official Gazette 1638. That opinion equally expressly excluded from patent protection "plants of the earth" and gems found in the earth. 1889 C.D. at 125. Gems of course are not alive.

By 1923, suggestions that patent protection be extended to plants had been made in several Congresses (App. A 57a, footnote 18). In an article in the *Journal of the Patent Office Society*, Thorne stated that patent protection was not granted to "plants and other natural products", citing *Latimer* and other opinions. "Re-

lation of Patent Law to Natural Products", 6 Journal of the Patent Office Society 23.

The Petitioner's suggestion that the legislative history of the 1930 Act does not support this theory perforce ignores both the very substantial objection to the original legislation by the Commissioner of Patents and the extensive response thereto in the Committee Reports. At the heart of both is the "product of nature" exclusion from patent protection. No reference is made to the "living thing" rejection on which reliance is placed by petitioner here. Hearings before the Committee on Patents, House of Representatives, 71st Cong., 2d Sess. on H.R. 11372, April 9, 1930, page 5, H. Rep. No. 1129, 71st Cong., 2d Sess. Part IV.

Nor does the legislative history of the Plant Variety Protection Act of 1970, a *non-patent* law, support petitioner's theory. All it shows is that plants are protected under the *patent* law only when asexually reproduced. Bacteria were expressly held not to be plants in *In Re Arzberger*, 112 F.2d 834 (CCPA 1940). In providing a different form of protection for sexually reproduced plants in 1970, the Congress merely carried forward the holding of *Arzberger*, by expressly excluding bacteria from that protection, 7 U.S.C. 2402 (App. A 63a).

There is no suggestion in the 1952 codification of the Patent Code that Congress intended to exclude all living things other than plants from patent protection. To the contrary, the House and Senate Reports on the 1952 Act indicate that a manufacture under 35 U.S.C. 101 "may include anything under the sun that is made by man". H. R. Rep. No. 1923, 82d Cong. 2d Sess. 6; U.S. Code Cong. & Admin. News 1952, p. 2409.

Chakrabarty's bacterium was made by man. No significant authority indicates that Congress intended the patent incentive to be withheld from such a manufacture because it is alive.

Not only has appropriate judicial consideration been given to the question here involved, but also the answer to that question by the Court below was correct.

CONCLUSION

The petition should be denied.

Respectfully submitted,

EDWARD F. MCKIE, JR.
LEO I. MALLOSSI

Attorneys for Respondent

Of Counsel:

JAMES C. DAVIS, JR.
JOSEPH B. FORMAN
JOSEPH T. COHEN

IN THE
Supreme Court of the United States

OCTOBER TERM, 1978

No. 79-136

LUTRELLE F. PARKER, Acting Commissioner of
Patents and Trademarks, *Petitioner*,

vs.

MALCOLM E. BERGY, et al., *Respondents*.

LUTRELLE F. PARKER, Acting Commissioner of
Patents and Trademarks, *Petitioner*,

vs.

ANANDA M. CHAKRABARTY, *Respondent*.

**BRIEF FOR RESPONDENTS MALCOLM E. BERGY,
ET AL., IN OPPOSITION TO PETITION FOR WRIT OF
CERTIORARI TO THE UNITED STATES COURT OF
CUSTOMS AND PATENT APPEALS**

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Of Counsel

JOHN KEKICH

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IN THE
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LUTRELLE F. PARKER, Acting Commissioner of
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LUTRELLE F. PARKER, Acting Commissioner of
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ANANDA M. CHAKRABARTY, *Respondent*.

**BRIEF FOR RESPONDENTS MALCOLM E. BERGY,
ET AL., IN OPPOSITION TO PETITION FOR WRIT OF
CERTIORARI TO THE UNITED STATES COURT OF
CUSTOMS AND PATENT APPEALS**

Respondents, Malcolm E. Bergy et al., oppose the
petition for writ of certiorari to the United States
Court of Customs and Patent Appeals.

QUESTION PRESENTED

Petitioner's statement of the question presented for
review should be replaced by the statement of the issue

made by the Court below. The Court below recognized the issue as

"... Is a man-made, biologically-pure culture of a microorganism, for industrial use in manufacturing an antibiotic, whose properties were discovered by the applicant for patent, excluded from the terms 'manufacture' and 'composition of matter' in 35 USC 101 because the microorganism is alive?" (P.¹ App. A 45a).

The Court below found that the Petitioner's statement

"... is overly broad, which is calculated to magnify its importance. We are not dealing with all living things, including man, fruits, vegetables, and flowers—all 'organisms.' ... To give a homely simple analogy, it is like asking whether a yeastcake or dried yeast powder is a 'manufacture' or 'composition of matter'. Yeast is alive." (P. App. A 45a).

STATUTE INVOLVED

The only statute involved in rejecting the claimed subject matter as nonstatutory is 45 U.S.C. § 101 (P. 3).

Reference in the Petition to the Plant Patent Act of 1930 (P. 3) is misleading because the application for the invention of the present case was *not* filed in the United States Patent and Trademark Office under said Act.

STATEMENT OF THE CASE

This case concerns a man-made biologically pure culture of a novel microorganism. A patent application

¹ "P." refers to the Petition for Writ of Certiorari to the United States Court of Customs and Patent Appeals filed in the present case.

was filed by the respondents in the United States Patent and Trademark Office on June 10, 1974. The invention is claimed in the patent application by two types of claims. The first type of claim is a *process* claim using the biologically pure culture of the novel microorganism to make the useful antibiotic lincomycin. The second type of claim is directed to the biologically pure culture of the novel microorganism itself. The Patent Examiner allowed the process claims,² but rejected the claim to the biologically pure culture of the novel microorganism under 35 U.S.C. § 101.³ On appeal, this rejection was affirmed by the United States Patent and Trademark Office Board of Appeals. The decision by the Board of Appeals was reversed by the United States Court of Customs and Patent Appeals in a decision handed down on October 6, 1977. *In re Bergy et al.*, 563 F.2d 1031 (1977).

On June 26, 1978, this Court granted a petition for a writ of certiorari filed by the Solicitor General seeking review of the Court of Customs and Patent Appeals' decision, vacated the judgment and remanded the case to the Court of Customs and Patent Appeals "for further consideration in light of *Parker v. Flook*, 437 U.S. 584" (438 U.S. 902).

The Court of Customs and Patent Appeals reaffirmed its initial decision. *In re Bergy et al.*, 596 F.2d 952

² Four process claims were allowed. Similar process claims are found in hundreds of U.S. patents relating to the production of antibiotics.

³ Both the allowed claims and the rejected claim recite a living microorganism. This living microorganism is the *same* in both instances, and it is characterized by a single disclosure in the patent application covering twelve (12) pages of the record filed in the United States Court of Customs and Patent Appeals (R. 8-19).

(1979). However, this time, the majority consisted of four judges, with one dissent, as compared to the initial 3-2 decision. (P. App. A 1a-70a). The majority discussed *Parker v. Flook*, *supra*, as follows:

"*Flook* was concerned only with the question of what is a 'process' under § 101, in the context of computer program protection. No such issue is presented in either of these appeals.

"There is no better authority on what the Supreme Court has decided in a case than the Court itself and we are fortunate to have its own summary of what it decided in *Flook*. It appears at the end of footnote 18, 437 U.S. at 595, as follows:

'Very simply, our holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101.'

"We do not venture to elaborate. The appeals here involve no method of calculation, and the *Flook* holding appears to have no bearing.

"As indicated earlier, we deem it our duty to seek whatever additional light there may be in the Court's opinion on the meaning of § 101, without restricting ourselves to the holding. It is stated to be well established in patent law that the following are not within the statutory categories of subject matter enumerated in § 101 and its predecessor statutes as interpreted through the years: principles, laws of nature, mental processes, intellectual concepts, ideas, natural phenomena, mathematical formulae, methods of calculation, fundamental truths, original causes, motives, the Pythagorean theorem, and the computer-implementable method claims of Benson and Tabbot. The present appeals do not involve an attempt to patent any of these things and the Court's review of this hornbook law is, therefore, inapplicable to the issue before

us, which involves only the construction of the terms 'manufacture, or composition matter'." (P. App. A 22a).

The majority analyzed the holding in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), which was cited in *Flook*, and compared it with the facts of the subject case. (P. App. A 24a-25a). A clear distinction was found.

"... The respondent in *Deepsouth* was asking the Court to expand established patent rights territorially, or to treat making parts of a machine as making the machine, by modifying prior cases construing the patent statutes. The Court refused, producing the quoted passage [P. App. A 25a] in the process.

"We do not find the quoted passage to have any bearing on our problem. We are not faced with a litigant urging upon us a construction of § 101 which is at odds with established precedent. Rather, we deal with a case of first impression. Not having been asked to make a change in existing law or to overrule or modify any case or to expand any right given by Congress, we need in this case no signal from that body." (P. App. A 25a).

Thus, the majority stated:

"To conclude on the light *Flook* sheds on these cases, very simply, for the reasons we have stated, we find none." (P. App. A 26a).

ARGUMENT

The Respondents respectfully submit that this case does *not* merit the granting of a writ of certiorari, because the decision by the United States Court of

Customs and Patent Appeals (hereinafter referred to as *Bergy*)

- (1) is *not* in conflict with any decision of another court on the same issue;
- (2) does *not* extend the patent laws; and,
- (3) is *not* inconsistent with the principles of construction of the patent law recently restated in *Parker v. Flook*, 437 U.S. 584 (1978).

In summary, there are *no special* and *important* reasons for granting a writ of certiorari in this case.

***Bergy* Is Not In Conflict With Any Other Decision**

Since the subject case is one of first impression in the courts, "there is no prior precedent to be extended or overruled, —." (P. App. A 64a). Accordingly, the writ of certiorari is not necessary to resolve a conflict of decisions among the courts.

***Bergy* Does Not Extend The Patent Laws**

Though the issue of this case was previously not before a court, it is a fact that it has been before the United States Patent and Trademark Office (PTO) for a long time. (P. App. A 64a-67a). Many patents have been issued by the PTO with claims drawn to, for example, (a) a composition containing oil and *Bacillus thuringiensis* (which is a "living microorganism"), (b) dry baker's viable yeasts (also a "living microorganism"), etc. (P. App. A 66a). In view of this history of the PTO issuing patents claiming living microorganisms, the argument that *Bergy* extends the patent law is unavailable as support for the granting

of a writ of certiorari. As succinctly stated by the majority in *Bergy*

"It is not possible to reconcile the assertion that we are 'expanding' patent law to cover living things with the PTO's issuance of the foregoing patents. Neither is it possible to reconcile the contention with the performance of the PTO in the very case before us." (P. App. A 67a).

***Bergy* Is Not Inconsistent With Accepted Principles of Construction of The Patent Law**

As evidenced by its thorough and scholarly opinion, the *Bergy* majority was very careful in considering the facts of this case in the light of *Flook*. It is inconceivable that the majority opinion can now be questioned as being inconsistent with *Flook* (P. 11), or that it "rejected the principles of construction of the patent law recently restated" in *Flook* (P. 8). The *Bergy* majority carefully distinguished *Flook* from the *Bergy* facts. (P. App. A 20a-26a). Their incisive analysis meets the highest test of legal review; it merits support, not criticism.

In addition to distinguishing *Flook* from *Bergy*, the *Bergy* majority expertly detailed the "Anatomy of the Patent Statute" to place the entire matter of interpreting the Patent Statute in its proper perspective. (P. App. A 10a-20a). Again, this is further evidence of the *Bergy* majority's exercise of the highest degree of care in deciding *Bergy*.

Since the argument of the pertinency of the Plant Patent Act to *Bergy* facts was advanced by the PTO, the *Bergy* majority carefully and exhaustively ana-

lyzed and laid to rest this untenable position. (P. App. A 49a-64a). As the *Bergy* majority stated:

"The principal mistake of the PTO was to look to the legislative history of the Plant Patent Act for evidence of the intent of a *previous* Congress, saying, in effect, that if Congress in 1930 passed an act extending patent protection to plant breeders, then Congress in 1874 must not have intended that 'manufactures' and 'compositions of matter' in R.S. § 4886 include *any* living organism. The violence done by this analysis resides in ascribing to a preceding Congress an intent that the members of that Congress did not themselves state. It is for this reason that the Supreme Court has consistently and unequivocally concluded that:

'[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one.'

"*United States v. Price*, 361 U.S. 304, 313 (1960); *accord*, *United States v. Southwestern Cable Co.*, 392 U.S. 157, 170 (1968); *United States v. Philadelphia National Bank*, 374 U.S. 321, 348-49 (1963); *Rainwater v. United States*, 356 U.S. 590 (1958); *United States v. United Mine Workers*, 330 U.S. 258, 281-82 (1947). In response to an argument remarkably similar to that made here by the PTO, the Supreme Court, in *Rainwater v. United States*, *supra*, 356 U.S. at 593, rejected an invitation to interpret the meaning of an act of Congress by reliance on a later amending act with the following comment:

'At most, the * * * amendment is merely an expression of how * * * [a later] Congress interpreted a statute passed by another Congress more than half a century before. Under these circumstances such interpretation has very little, if any, significance.'" (P. App. A 51a).

The *Bergy* majority found that the purpose of Congress in enacting the Plant Patent Act "... was precisely what Congress said it was—to offer to the useful art of *plant breeding* in the fields of horticulture and agriculture the benefits of the patent system that had theretofore been available only to industry." (P. App. A 59a).

CONCLUSION

The above clearly shows that there are *no special* and *important* reasons for granting a writ of certiorari in this case. The raising of emotional points by Petitioner does *not* make the case special or important. Emotional exhortations bottomed upon sheer speculation of future legal problems, and an apparent lack of understanding of the true benefits and risks of microbiological inventions, cannot be relied upon as a guiding force in the administration of the Patent Law.

The *Bergy* majority has resolved the issue in a way which benefits the public and the inventor, a solution which is completely in accord with the Patent Law. There is clearly no basis or need to review the issue further.

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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301 Henrietta Street
Kalamazoo, Michigan 49001

*Attorney for Respondents
Malcolm E. Bergy, et al.*

Of Counsel

JOHN KEKICH

No. 79-136

OCT 11 1979

FILED

CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1979

**LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS, PETITIONER**

v.

MALCOLM E. BERGY, ET AL.

**LUTRELLE F. PARKER, ACTING COMMISSIONER
OF PATENTS AND TRADEMARKS, PETITIONER**

v.

ANANDA M. CHAKRABARTY

**ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF CUSTOMS AND
PATENT APPEALS**

REPLY MEMORANDUM FOR THE PETITIONER

WADE H. MCCREE, JR.
Solicitor General
Department of Justice
Washington, D.C. 20530

In the Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-136

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v.

ANANDA M. CHAKRABARTY

*ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF CUSTOMS AND
PATENT APPEALS*

REPLY MEMORANDUM FOR THE PETITIONER

1. Respondents contend that the decisions below did not extend the coverage of the patent laws because patents have previously been issued for living things (Bergy Op. 6-7; Chakrabarty Op. 8). But although such patents may occasionally have been granted,¹ those

¹Some of the patents cited by respondents and the Court of Customs and Patent Appeals claim a virus, which some scientists consider to be without life (Pet. App. 66a-67a, Nos. 5, 8). See Weaver, *The Cancer Puzzle*, 150 Nat'l Geographic 396, 397 (Sept. 1976); Gore, *The Awesome Worlds Within a Cell*, 150 Nat'l Geographic 355, 386 (Sept. 1976).

grants represent aberrations, rather than any settled agency interpretation of the patent laws. This Court has remarked on "the free rein often exercised by Examiners in their use of the concept of 'invention.'" *Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966). This "free rein" is the inevitable result not only of the large number of patent applications processed each year by the patent examining corps,² but also of the patent statutes, which provide no procedure for administrative review of an examiner's decision to grant a patent. 35 U.S.C. 7, 131, 134; see *Watson v. Bruns*, 239 F. 2d 948 (D.C. Cir. 1956). For these reasons, isolated grants of patents by patent examiners are not entitled to the usual weight given to the administrative interpretation of a statute. *Andrews v. Hovey*, 124 U.S. 694, 716-718 (1888).

The Board of Appeals has consistently denied patents on claims drawn to living things themselves (see, in addition to the present cases, *In re Merat*, 519 F. 2d 1390, 1393 (CCPA 1975)). As noted in our petition, the issue is one of first impression in the courts (Pet. 8).

2. Respondent Chakrabarty also contends (Op. 10-12) that Congress found it necessary to pass the Plant Patent Act of 1930 not because plants as living things fell outside the scope of patentable subject matter but because plants were believed to be unpatentable as products of nature. He bases this argument primarily³ on the assertion that

²The Patent and Trademark Office granted 70,320 patents in FY 1978. A staff of 1,064 professional employees worked there at that time, mostly in the patent examining corps. *Commissioner of Patents and Trademarks, Annual Report FY 1978* 12, 30 (1979).

³He also relies on *Ex Parte Latimer*, 1889 C. D. 123, and an article published in the *Journal of the Patent Office Society* in 1923 (Chakrabarty Op. 11-12). Whatever the positions adopted in those materials, there is no evidence that Congress was even aware of them, much less shared any views expressed therein.

the Commissioner of Patents made "very substantial objection" to the original plant patent legislation on the basis that plants were products of nature (Op. 12). The legislative history of the Plant Patent Act shows, however, that the Commissioner's objection was only to that part of the original bill which would have extended patent protection to already existing plants, not to the extension of such protection to plants created by botanists and horticulturists.⁴ Thus, the Commissioner specifically

⁴The first Senate and House bills, which extended patent protection to "any person who invented or discovered * * * any new and distinct variety of asexually reproduced plant" both contained the following proviso:

*Provided, That the words "invented" and "discovered" * * * in regard to asexually reproduced plants, shall be interpreted to include invention and discovery in the sense of finding a thing already existing and reproducing the same as well as in the sense of creating. [S. 3530, 71st Cong., 2d Sess. § 4886 (1930); H.R. 9765, 71st Cong., 2d Sess. § 4886 (1930) in R. Allyn, THE FIRST PLANT PATENTS 60 (1934).]*

In a memorandum included in the record of the House hearings, the Commissioner of Patents distinguished between those varieties of plants found in nature and then asexually reproduced and those new varieties "created, for example, by cross pollination resulting from human efforts * * *." *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 6 (1930) (Memorandum of Commissioner Thomas E. Robertson). He had no objection to patenting plant varieties created by plant breeders, nurserymen and horticulturists since such varieties were not produced by natural processes. The Commissioner objected only to patenting those plant varieties "reproduced by operation of nature, aided only by the act of the patentee in grafting it by the usual methods * * *" (emphasis in original) (*ibid.*). He did not think such products of nature satisfied the constitutional requirement of invention (*ibid.*).

The language to which the Commissioner objected was not in the version of the bill reported out of committee. H.R. Rep. No. 1129, 71st Cong., 2d Sess. 11 (Appendix B) (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 10 (Appendix B) (1930).

recognized that some plants are created by man, and are thus *not* products of nature. He nevertheless concluded that such plants were not then patentable; he agreed that the patent laws should be extended to make it possible to grant patents for such plants. *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 6 (1930) (Memorandum of Commissioner Thomas E. Robertson). The Commissioner's views therefore accorded with those of the Secretary of Agriculture, who told the congressional committees that the patent laws then covered "only inventions and discoveries in the field of inanimate nature." H.R. Rep. No. 1129, 71st Cong., 2d Sess. 10 (Appendix A) (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 9 (Appendix A) (1930).⁵

For the reasons stated herein and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

WADE H. MCCREE, JR.
Solicitor General

OCTOBER 1979

⁵Respondent Chakrabarty discounts the views of the Secretary of Agriculture on the ground that he was "not shown to have any expertise in the patent law" and because his interpretation was "not shown to have had any impact on the Congress" (Op. 11). On the contrary, the Secretary's letter was appended to the Committee reports. H.R. Rep. No. 1129, 71st Cong., 2d Sess. 10 (Appendix A) (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 9 (Appendix A) (1930). While the Secretary's views on the existing law's coverage were not discussed in the Committee reports themselves, both reports referred to his letter in connection with other matters. H.R. Rep. No. 1129, *supra*, at 3, 6; S. Rep. No. 316, *supra*, at 3, 5.

DEC 20 1979

MICHAEL ROBAK, JR., CLERK

IN THE
Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-136

LUTRELLE F. PARKER, Acting Commissioner of
Patents and Trademarks, *Petitioner*,

v.

MALCOLM E. BERGY, et al., *Respondents*.

LUTRELLE F. PARKER, Acting Commissioner of
Patents and Trademarks, *Petitioner*,

v.

ANANDA M. CHAKRABARTY, *Respondent*.

On Writ of Certiorari to the
United States Court of Customs and Patent Appeal

MOTION TO DISMISS AND VACATE AS TO
RESPONDENTS MALCOLM E. BERGY, ET AL.

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December 20, 1979



United States Department of Justice
Office of the Solicitor General
Washington, D.C. 20530

RECEIVED

JAN 8 1980

OFFICE OF THE CLERK
SUPREME COURT, U.S.

January 8, 1980

Michael Rodak, Jr., Esquire
Clerk
Supreme Court of the United States
Washington, D. C. 20543

Re: Sidney A. Diamond, Commissioner of Patents
& Trademarks v. Malcolm E. Bergy, et al.
No. 79-136

Dear Mr. Rodak:

A motion to dismiss and vacate has been filed by respondents Bergy, et al., in this case. That motion reports that the patent application involved in the Bergy case has been formally abandoned, and thus that case has become moot. It accordingly asks this Court to vacate the Bergy judgment, and remand that case to the Court of Customs and Patent Appeals with directions to dismiss the appeal as moot.

We agree with this proposed disposition of the case; since the abandonment of the patent application has mooted the case, review by this Court of the Court of Customs and Patent Appeals' judgment is no longer appropriate. Cf. Dann v. Noll, 434 U.S. 875 (1977). This action will, of course, have no effect on the status of the companion case, Diamond v. Chakrabarty, which remains pending in No. 79-136.

Sincerely,

Wade H. McCree, Jr.
Wade H. McCree, Jr.
Solicitor General

IN THE
Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-136

LUTRELLE F. PARKER, Acting Commissioner of
Patents and Trademarks, *Petitioner*,

v.

MALCOLM E. BERGY, et al., *Respondents*.

LUTRELLE F. PARKER, Acting Commissioner of
Patents and Trademarks, *Petitioner*,

v.

ANANDA M. CHAKRABARTY, *Respondent*.

MOTION TO DISMISS AND VACATE AS TO
RESPONDENTS MALCOLM E. BERGY, ET AL.

Respondents Malcolm E. Bergy et al, by filing an Amendment (Appendix A) with the United States Patent and Trademark Office on December 19, 1979, have abandoned the subject matter of this appeal insofar as it applies to those respondents.

In view of the abandonment of the Bergy et al. subject matter, the controversy is now moot as to those respondents. See *Brenner v. Hofstetter*, 389 U.S. 5 (1967). Respondents Bergy et al therefore move that the judgment (insofar as it applies to those respondents) be vacated and the case remanded to the United States Court of Customs and Patent Appeals with directions to dismiss the appeal to that court as moot.

Respectfully submitted,

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*Attorneys for Respondents
Malcolm E. Bergy et al.*

December 20, 1979

1a

APPENDIX A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of
MALCOLM BERGY ET AL
Serial No.: 477,766
Filed: June 10, 1974
For: PROCESS FOR PREPARING LINCOMYCIN

Attention: Solicitor
By Hand Delivery

AMENDMENT

Hon. Commissioner of Patents and
Trademarks
Washington, D.C. 20231

Sir:

Kindly amend the above captioned application as follows:

IN THE CLAIMS:

Cancel claim 5.

REMARKS

Via the above amendment applicants have abandoned the subject matter of the pending appeal at the Supreme Court, *Parker v. Bergy*. With the cancellation of all subject matter in

2a

controversy at the Supreme Court, the application is in condition for allowance.

Respectfully submitted,
MALCOLM BERGY ET AL

by

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In the Supreme Court of the United States

OCTOBER TERM, 1979

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, PETITIONER

v.

MALCOLM E. BERGY, ET AL.

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, PETITIONER

v.

ANANDA M. CHAKRABARTY

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEALS

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BRIEF FOR THE PETITIONER

OPINIONS BELOW

The most recent opinion of the Court of Customs and Patent Appeals (Pet. App. A, 1a-103a) in these cases is reported at 596 F.2d 952.

(1)

The order of this Court remanding *Parker v. Bergy* to the Court of Customs and Patent Appeals is reported at 438 U.S. 902. The prior opinion of the Court of Customs and Patent Appeals in that case (Pet. App. C, 106a-128a) is reported at 563 F.2d 1031. The opinion of the Patent and Trademark Office Board of Appeals (Pet. App. D, 129a-139a) is reported at 197 U.S.P.Q. 78. The opinion of the patent examiner (Pet. App. E, 140a-141a) is not reported.

The prior opinion of the Court of Customs and Patent Appeals in the second case, *Application of Chakrabarty* (Pet. App. F, 142a-158a) is reported at 571 F.2d 40. The opinions of the Patent and Trademark Office Board of Appeals (Pet. App. G, 159a-164a; Pet. App. I, 168-169a) and of the patent examiner (Pet. App. H, 165a-167a) in that case are not reported.

JURISDICTION

The judgments of the Court of Customs and Patent Appeals were entered on March 29, 1979 (Pet. App. B, 104a-105a). On June 13, 1979, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including July 27, 1979. The petition was filed on that date, and granted on October 29, 1979. The jurisdiction of this Court rests on 28 U.S.C. 1256. *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Dann v. Johnston*, 425 U.S. 219 (1976).

QUESTION PRESENTED

Whether a living organism is patentable subject matter under 35 U.S.C. 101.

STATUTES INVOLVED

35 U.S.C. 101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Plant Patent Act of 1930, 35 U.S.C. 161, provides in relevant part:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor * * *.

Section 42(a) of the Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1547, 7 U.S.C. 2402(a), provides in relevant part:

The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor * * *.

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STATEMENT

A. Bergy

In 1974, Malcolm E. Bergy and two other scientists applied for a patent (A. 4-26), assigned to the Upjohn Company (Pet. App. 4a), with four claims to a process for preparing the antibiotic lincomycin using a newly isolated microorganism, *Streptomyces vellosus* ("S. vellosus") (A. 22)¹ and a fifth claim for a culture of *S. vellosus* itself, as follows (A. 25):

A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

The examiner allowed claims 1-4 (the process claims), and his decision on those claims is not in dispute (Pet. App. 27a, 140a). He rejected claim 5, however, on the basis that *S. vellosus* is a product of nature and thus not patentable (Pet. App. 140a).

The Board of Appeals, with one member dissenting, sustained the rejection of claim 5 on the ground that a living organism is not patentable subject matter under 35 U.S.C. 101 (Pet. App. 129a-139a).

¹ This microorganism was found in Arizona soil samples (A. 6, 9) and a subculture, supplied by Upjohn, is permanently maintained by the Department of Agriculture at its research facilities. It is identified by its accession number, NRRL 8037 (A. 6).

The Board found support for this view in the Plant Patent Act of 1930, 35 U.S.C. 161 *et seq.* It reasoned that Congress would not have specifically given patent protection under the 1930 Act to certain kinds of plants if it had believed that patents could already be obtained for these plants, as living organisms, under the general patent laws, Rev. Stat. 4886, now 35 U.S.C. 101 (Pet. App. 130a-132a).²

The Court of Customs and Patent Appeals reversed, with two judges dissenting (Pet. App. 106a-128a). The court reasoned that, since patents are available for processes using a strain of living bacteria (*e.g.*, in septic systems or to produce alcohol), it would be "illogical" to insist that the living bacteria in a biologically pure culture are not themselves statutory subject matter (Pet. App. 118a).

On June 26, 1978, this Court granted a petition for a writ of certiorari filed by the Solicitor General seeking review of the Court of Customs and Patent Appeals' decision, vacated the judgment and remanded the case to the Court of Customs and Patent Appeals "for further consideration in light of *Parker v. Flook*, 437 U.S. 584" (438 U.S. 902).

B. Chakrabarty

On June 7, 1972, Ananda Chakrabarty filed a patent application (A. 40-84), assigned to the General

² It did not reach the "product of nature" issue upon which the examiner's decision rested. The dissenting Board member concluded that claim 5 involved a "composition" or "manufacture" and was accordingly patentable under 35 U.S.C. 101 (Pet. App. 132a).

Electric Company, with 36 claims to, *inter alia*, a strain of bacteria from the genus *Pseudomonas*, and an inoculum consisting essentially of these bacteria (A. 72-74). Certain strains of *Pseudomonas* bacteria existing in nature are capable of degrading by enzymatic reactions a particular component of a complex hydrocarbon, such as crude oil, but no known naturally-occurring bacterium can degrade more than one such component. Chakrabarty employed so-called "genetic engineering" to develop a *Pseudomonas* bacterium capable of degrading more than one component of crude oil (Pet. App. 142a-143a).³

Although the examiner allowed claims for the process by which incompatible plasmids present in a *Pseudomonas* bacterium are fused to render them compatible,⁴ he rejected the claims for the genetically engineered *Pseudomonas* bacteria themselves, apparently on two grounds: (1) the microorganisms are

³ Plasmids, which are hereditary units separate from the chromosomes, carry the hydrocarbon-degrading capacity of the cell. Chakrabarty utilized a process of natural conjugation (A. 41, 46) to effectuate the transfer to a single cell of plasmids from various known strains of bacteria, each known to have a specific capacity to degrade a particular component of crude oil (A. 46-50). The resulting organism, which Chakrabarty seeks to patent, is a bacterium with increased hydrocarbon-degrading capacities due to the different kinds of plasmids it contains (Pet. App. 143a).

⁴ The examiner also allowed claims 30-32 and 35-36, which were for an inoculum comprised of a carrier material able to float on water and of *Pseudomonas* bacteria containing at least two plasmids, each providing a separate hydrocarbon-degrading pathway (A. 88).

"products of nature"; and (2) as living organisms they are not patentable subject matter under 35 U.S.C. 101 (Pet. App. 165a-167a; A. 87).

The Board of Appeals affirmed the examiner on the second ground (Pet. App. 160a-163a).⁵ Relying on the legislative history of the Plant Patent Act, the Board reasoned that the terms "manufacture" or "composition of matter" in 35 U.S.C. 101 were not intended to cover living organisms (Pet. App. 161a-162a). The Board also observed that if 35 U.S.C. 101 were interpreted to encompass genetically-modified bacteria, it could also be read to encompass modified living multicellular organisms (*ibid.*).

The Court of Customs and Patent Appeals reversed, with two judges again dissenting (Pet. App. 142a-158a). The majority found the case indistinguishable from *Bergy* (Pet. App. 147a-148a).

On July 26, 1978, the Solicitor General filed a petition for a writ of certiorari seeking review of the Court of Customs and Patent Appeals' decision (No. 78-145). Shortly thereafter, however, that court vacated its earlier judgment, recalled its mandate and restored the appeal to the calendar. On August 25, 1978, pursuant to the parties' stipulation, the petition for a writ of certiorari was dismissed (Pet. App. 5a-6a).

⁵ The Board rejected the product-of-nature theory partially relied upon by the examiner, noting that *Pseudomonas* bacteria containing two or more hydrocarbon-degrading plasmids are not naturally occurring (Pet. App. 163a).

C. The Decision After Remand

The Court of Customs and Patent Appeals reaffirmed its earlier judgments in both cases (Pet. App. 40a, 70a).⁶ The majority discussed *Parker v. Flook*, 437 U.S. 584 (1978), which it distinguished as being “concerned only with the question of what is a ‘process’ under § 101”, an issue unrelated to the appeals before it (Pet. App. 22a). It found the holding in *Flook*—that an improved method of calculation is unpatentable under Section 101—similarly inapplicable (*id.* at 22a). Stressing that there was “no formula, algorithm, or law of nature” involved here (Pet. App. 23a), the Court of Customs and Patent Appeals summarized: “[t]o conclude on the light *Flook* sheds on these cases, very simply * * * we find none” (*id.* at 26a).⁷ It therefore adhered both to the analysis and the conclusion in its earlier decisions, emphasizing that the plain language of Section 101 does not distinguish between living and inanimate matter (*id.* at 44a-45a, 64a-65a, 69a), and that microorganisms should be treated no differently under Section 101 than chemical compounds (*id.* at 45a).⁸

⁶ The court, though not formally consolidating the cases, heard and decided them together because they involved “the same single question of law” (Pet. App. 2a).

⁷ It nevertheless asserted that *Flook* contained “an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated” (Pet. App. 10a), and adopted a “novel * * * doctrine” with “potential for great harm to the incentives of the patent system” (*id.* at 23a-24a).

⁸ In a separate concurrence, Judge Baldwin found that the precedents cited in *Parker v. Flook* defined an area where

Judge Miller, dissenting, stated that the majority had read *Parker v. Flook*, *supra*, too narrowly. He interpreted the decision in *Flook* as requiring a clear and certain signal from Congress where there is substantial doubt that Congress intended to include a particular development as patentable subject matter under Section 101. From his reading of the legislative history of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, Judge Miller found at least a substantial doubt about Congress’ intent to include living things within the scope of patentable subject matter in Section 101 (Pet. App. 96a). Accordingly, in the absence of any clear and certain signal that they were to be included, the courts should not bring them within the bounds of Section 101 by unwarranted judicial construction of the statutory language (*ibid.*).

SUMMARY OF ARGUMENT

Under this Court’s decisions, the patent laws are to be strictly construed in light of the basic national economic policy against monopoly, and in order to reserve to Congress decisions concerning extension of the patent laws into new areas. Congress, rather

patents were not possible because “the inventor attempted to preclude others from using those bare [natural] phenomena” (Pet. App. 88a). He observed that in the instant cases the inventions did not “reach out to encompass natural phenomena * * *, but rather recite only non-naturally occurring compositions of matter that are but single tools for utilizing natural phenomena in producing new and useful end results” (Pet. App. 91a).

than the judiciary, is empowered and is best able to resolve the complex social, economic, and scientific questions frequently involved in such decisions, and, if an extension is to be made, to tailor the statute to achieve precisely the desired ends. The determination whether living organisms produced by "genetic engineering" of the kind involved in Chakrabarty's invention should themselves be patentable is just such a decision. It involves social, economic and scientific questions of great complexity. Moreover, if Congress should decide to extend patent protection to such inventions, it might well decide to do so by a specifically tailored statute, similar to those it has provided for certain hybridized plants, rather than by providing generally for the patentability of living organisms under the basic patent law.

Congress has not yet made that determination. Indeed, the only specific reference to bacteria in the relevant statutes provides that they are *not* to receive patent-type protection (7 U.S.C. 2402). Until the instant cases, it was generally assumed by the legal profession, writers on the subject, and Congress, that the patent law's provision (35 U.S.C. 101) for the patentability of a new and useful "manufacture, or composition of matter" did not permit the patenting of living organisms.⁹ Congress acted on this assump-

⁹ The Commissioner and the Board of Appeals have consistently so interpreted Section 101, although there have been occasional, aberrant decisions by individual Patent Office Examiners. Since the decision to issue a patent is not administratively reviewable, these aberrant decisions have resulted in a few instances in the issuance of patents for living organisms.

tion when it enacted the Plant Patent Act (R.S. (35 U.S.C. 161 *et seq.*) in 1930, and when it extended patent-type protection to other varieties of plants in the Plant Variety Protection Act, 7 U.S.C. 2321 *et seq.* in 1970.

The legislative history of both Acts clearly indicates that Congress intended to extend the protections of the patent laws to previously unprotected agricultural inventions. Inanimate inventions relating to agriculture had always been covered by the patent law; the only reason that legislation was required was because the subjects to be newly protected were alive.

Neither the 1930 nor the 1970 Act permits the patenting of naturally occurring plants that have simply been found by their claimed discoverer. Both Acts require that the inventor must, like Chakrabarty, have actually developed the new variety by creating a hybrid form that does not exist in nature. New legislation was necessary to permit the patenting of such newly created plants.¹⁰ That legislation does not encompass Chakrabarty's invention; accordingly, it is not patentable.

¹⁰ As the CCPA noted, patents for processes involving living organisms have long been issued. But that does not suggest that the organisms themselves are patentable, since a process using unpatentable elements or producing an unpatentable end product is patentable so long as the process itself qualifies under the patent law.

ARGUMENT

I. ABSENT A CLEAR CONGRESSIONAL INTENT TO AFFORD PATENT PROTECTION TO LIVING ORGANISMS, THE PATENT STATUTE SHOULD NOT BE INTERPRETED TO EXTEND COVERAGE TO NEW LIFE FORMS

This Court only recently held that the judiciary "must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress." *Parker v. Flook*, 437 U.S. 584, 596 (1978). In such cases, the patent laws will not be held to apply unless there is "a clear and certain signal from Congress", for such an extension makes "the beachhead of [monopoly] privilege * * * wider, and the area of public use narrower * * *." *Id.* at 596. This ruling was a reflection of the general principle that, because of "this Nation's historical antipathy to monopoly", the patent laws are strictly construed. *Deepsouth Packing Company v. Laitram Corp.*, 406 U.S. 518, 530 (1972); see also *Sears, Roebuck & Company v. Stiffel Company*, 376 U.S. 225, 230 (1964); *Graham v. John Deere Company*, 383 U.S. 1, 7 (1966). Strict construction serves a function beyond confining monopoly, moreover. Decisions on whether and how to extend the patent monopoly require policy judgments involving economic and scientific considerations. Congress is the governmental institution that is empowered and best able to make such decisions. *Parker v. Flook*, *supra*, 437 U.S. at 595-596. This proceeding offers a virtual case study justifying the application of those principles.

As the Court of Customs and Patent Appeals readily acknowledged, the question involved is an issue of first impression (Pet. App. 68a). Thus, almost 190 years after the first patent statute was enacted and after numerous amendments to the basic law, the court's decision is the first holding by any court that living organisms are themselves either a "manufacture" or a "composition of matter" and thus patentable. Indeed, until the decision below, it was the general understanding that patent coverage was not available and that legislation was needed if patent protection was to be extended to microorganisms. The only judicial pronouncements on the subject suggested that living things are not themselves patentable. *Guaranty Trust Company v. Union Solvents Corporation*, 54 F.2d 400, 410 (D. Del. 1931), *aff'd*, 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933). The CCPA had itself so indicated. *Application of Mancy*, 499 F.2d 1289, 1294 (C.C.P.A. 1974).¹¹ The Patent, Trademark and Copyright Law

¹¹ The CCPA in *Mancy* "presumed" that the applicants would have been "unable to obtain [an allowed] claim [for a novel strain of *Streptomyces*] because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature.'" *Mancy*, *supra*, 499 F.2d at 1294. In the instant cases the CCPA suggested that this dictum meant only that the claim lacked novelty because the microorganism was "plucked from the earth" (Pet. App. 46a). But the *Mancy* court surely meant the "product of nature" language in a sense broader than simply a thing found in nature, unchanged by the hand of man, for *Mancy*'s production of the antibiotic daunorubicin using *Streptomyces bifurcus* involved a laboratory process of isolation and cultivation of the microorganism in a defined nutrient medium. *Mancy*, *supra*, 499 F.2d at 1290. It was thus like *Bergy's*

Section of the American Bar Association and its subcommittees repeatedly went on record as favoring new legislation to extend the scope of the patent laws so that various living things, including microorganisms, might at last be patented.¹² Writers

biologically pure culture of *Streptomyces vellosus*, which the same judges who decided *Mancy* found did "not define a product of nature" (Pet. App. 39a).

The issue of living organism patentability was raised, but not decided, in *Application of Merat*, 519 F.2d 1390, 1393 (C.C.P.A. 1975) (claim to a hybrid chicken produced by a specified process).

¹² In 1966, the American Bar Association Patent Section passed Resolution 22 entitled "Extension of Patent System to Biological Arts Not Now Covered" favoring coverage under the patent law for, among other things, "micro-organisms, and animal husbandry." ABA Patent, Trademark and Copyrights Law Section, 1966 *Summary of Proceedings* 59, 74 (1967).

In 1969, Subcommittee E of the ABA Patent Section reported, after studying "articles which advocated the extension of the Plant Patent Act to include micro-organisms," that "[t]here is a growing concern by many that the micro-biological art is ready to enjoy the fruits of the patent system [and that] [t]here is also a growing belief that the micro-biological art needs stimulation of the kind offered by a patent system." ABA Patent, Trademark and Copyright Law Section, 1969 *Committee Reports* 123 (1970).

In 1976 Committee 111 of the ABA Patent Section proposed another Resolution 22, which favored among other things "amendment of 35 U.S.C. 161 [defining the subject matter for plant patents] * * * to render patentable new forms of microorganisms." ABA Patent, Trademark and Copyright Law Section, 1976 *Committee Reports* 110 (1977). The proposed recommendation regarding microorganisms was not approved by the Section, however, apparently because the purpose of the resolution was to come within the pro-

on patent law agreed that a new statute was necessary, and some urged Congress to legislate.¹³

nouncements of a European treaty on plant patent protection (Union for the Protection of Obtentions Vegetal) and "it did not seem 100% essential that protection be given to microorganisms in order to do that." ABA Patent, Trademark and Copyright Law Section, 1976 *Summary of Proceedings* 95 (1977).

Similarly, the American Patent Law Association in 1967 adopted a resolution favoring the extension of the patent laws to "all the agricultural arts (including all plants * * * microorganisms and animal husbandry)." *Patent Law Revision: Hearings on S. 2, S. 1042, S. 1377, S. 1691, S. 2164, S. 2597 Before the Subcomm. on Patents, Trademarks and Copyrights of the Senate Comm. on the Judiciary*, Part 2, 90th Cong., 2d Sess. 549 (1968) (Statement of Eben M. Graves, President, American Patent Law Association). That association recommended the enactment of legislation to accomplish that extension. *Id.* at 546, 553.

¹³ The late John A. Dienner, a past president of the American Patent Law Association and a past Chairman of the ABA Patent Section, reported that in 1928 he conferred with Secretary of Agriculture Hyde, "with a view to providing legislation granting broad protection like that of a patent to all originators of plants and animals and products thereof * * *." Dienner, *Patents for Biological Specimens and Products*, 35 J. Pat. Off. Soc'y 286, 290 (1953). According to Dienner, "Secretary Hyde was enthusiastic, but the movement was kidnaped and disguised as the 1930 Plant Patent Act." *Ibid.* Other experts writing on the subject likewise thought that without additional legislation no patents could issue for living things, other than those plants covered under the Plant Patent Act. See, e.g., Rossman, *The Preparation and Prosecution of Plant Patent Applications*, 17 J. Pat. Off. Soc'y 632 (1935). In that article, former Patent Office Examiner Joseph Rossman argued: "The plant [patent] law should * * * logically be extended to all forms of plants without restriction as to method of reproduction or type. The next step would

Congress has not yet followed these recommendations for legislation. Should it consider doing so, it would be required to determine the scope of the patent protection (if any) to be provided, in light of the difficult and controversial policy questions involved in any extension of patent protection to living things.

The legislature has far more flexibility than the judiciary in making such determinations. It can, for example, decide, as it has done in the Plant Patent Act (35 U.S.C. 161 *et seq.*) and the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*), to extend the patent laws to specifically defined categories of living things. It can also tailor the precise limits of the protections available and the statutory requirements for obtaining those protections to reflect the particular attributes of the forms protected, as it has done in those Acts.¹⁴ See 35 U.S.C. 162, 163; 7 U.S.C. 2404, 2422, 2483(c), 2543, 2544. Cf. *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1379-1383 (5th Cir. 1976), cert. denied, 429 U.S. 1094 (1977); Jeffery, *The Patentability and Infringement of Sport Varieties: Chaos or Clarity?*, 59 J. Pat. Off. Soc'y 645, 654-657 (1977).

be to enact a law for patenting novel types of animal life." *Id.* at 644. And see Glascock and Stringham, *Patent Soliciting and Examining* 591 (1934); R. Allyn, *The First Plant Patents* 10 (1934).

¹⁴ For example, the reproductive ability of living things, and the small likelihood that even the most exact description of the method by which the originator developed his claimed invention will permit its duplication, mean that living things do not fit easily within the general patent statute. See *R. Allyn, supra, passim*.

The courts have much more limited options. Since both the Plant Patent Act and the Plant Variety Protection Act define with some precision the life forms to which they apply (35 U.S.C. 161; 7 U.S.C. 2401, 2402),¹⁵ the only way the courts can extend patent protection to other living organisms is by the route chosen by the CCPA—by concluding that "we do not see * * * any sound reason for making the distinction * * * between the living and the dead" (Pet. App. 65a; emphasis in original), and thus treating living organisms as precisely the same as any subject matter patentable under Section 101.¹⁶

Even if Congress were to limit its consideration of the desirability of extending patent protection to microorganisms, it would have to make difficult policy decisions with far-reaching effects. Chakrabarty's discovery is closely related to recombinant DNA re-

¹⁵ The organisms involved here are not patentable under those Acts. The Plant Variety Protection Act specifically excludes bacteria (7 U.S.C. 2402), and the Plant Patent Act applies only to the "invent[ion] or discover[y] and asexual reproduc[tion of] any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state." 35 U.S.C. 161. See *In re Arzberger*, 112 F.2d 834 (C.C.P.A. 1940).

¹⁶ Even the CCPA recognized elsewhere in its opinion that this "all or nothing" approach was not appropriate in dealing with living organisms, and disavowed any intent to suggest the patentability of life forms other than microorganisms (Pet. App. 45a). It failed, however, to suggest why its conclusion concerning the scope of Section 101 would not also apply to other living organisms, and, indeed, at least implicitly recognized that it would (Pet. App. 48a-49a, 64a-67a).

search¹⁷ and like that research involves "genetic engineering" (Pet. App. 143a).¹⁸

Research in this area is already highly controversial, in part because of the potential hazards involved.¹⁹ Microorganisms with transplanted genes, if allowed to escape into the environment or to infect

¹⁷ DNA (deoxyribonucleic acid) is the basic genetic material that determines the hereditary characteristics of the cell. Using enzymes that can break up designated DNA strands and couple the broken fragments in new combinations, microbiologists have been able to introduce foreign genes into bacteria or into a culture of cells in a test tube. See "Recombinant DNA Research: Guidelines Released by the National Institutes of Health," 41 Fed. Reg. 27902-27941 (1976). The agent (vector) used to effectuate the transfer of the DNA is a plasmid, the cell particle employed by Chakrabarty (Pet. App. 35a), or a virus. 41 Fed. Reg. 27903-27904 (1976). Cells containing recombinant DNA can be bred in a genetically homogeneous culture. Recombinant DNA Research, *Documents Relating to "NIH Guidelines for Research Involving Recombinant DNA Molecules," February 1975-June 1976*, 160-162, DHEW Pub. No. (NIH) 76-1138 (National Institutes of Health, Public Health Service (1976). Such cultures, or bacteria carrying the recombinant DNA, have potential for commercial use, for example, in the production of human hormones or organic chemicals, and in increasing the photosynthetic efficiency of plants. *Id.* at 4; Wade, *Recombinant DNA: Warming Up For Big Payoff*, 206 Science 663 (1979).

¹⁸ The CCPA spoke approvingly of the research being conducted by Genentech, Inc., which is attempting to exploit the commercial possibilities of recombinant DNA, and strongly implied that the microorganisms it is creating are patentable (Pet. App. 42a).

¹⁹ Moreover, as amicus Peoples Business Commission points out, there is the possibility that permitting patenting may actually lead to a reduction in the genetic diversity of the life forms involved. Brief 6-12.

laboratory workers and others, could be hazardous to man or to other life forms. See "Recombinant DNA Research: Guidelines Released by the National Institutes of Health," 41 Fed. Reg. 27904 (1976) (hereafter "Guidelines"); Brief on behalf of the Peoples Business Commission, 18-21. It was for this reason that the Director of the National Institutes of Health in 1976 released guidelines for NIH-sponsored research on recombinant DNA that established controlled conditions under which such research was to be performed. 41 Fed. Reg. 27902.²⁰ Continuing controversy over the degree of governmental control of recombinant DNA research²¹ has resulted in revisions of these guidelines.²²

²⁰ Comments were sought prior to the release of the guidelines. While some commentators found the guidelines adequate and others considered them onerous (41 Fed. Reg. 27904 (1976)), the Director reported that still others believed that the hazards posed were unique. *Ibid.* In their view, "the occurrence of an accident or the escape of a vector could initiate an irreversible process, with a potential for creating problems many times greater than those arising from the multitude of genetic recombinations that occur spontaneously in nature." *Ibid.* See 1 Recombinant DNA Research, *supra*, at 65-68, 134-139, 372-401. The guidelines treat the problem of physical isolation of research on recombinant DNA in the laboratory as well as limitations on the use of certain vectors. 41 Fed. Reg. 27904 (1976).

²¹ It was recently reported that Genentech and Eli Lilly have asked NIH for "permission to exceed the 10-liter limit now imposed on the amount of culture allowed in any recombinant DNA process." *Chemical Week* 34 (Sept. 26, 1979). Draft standards for such large scale research are being considered. 44 Fed. Reg. 63074, 63075 (1979).

²² See "Recombinant DNA Research: Revised Guidelines," released by the National Institutes of Health, 43 Fed. Reg.

One aspect of this controversy is the extent, if any, to which patent grants should be afforded on organisms that result from genetic engineering. Some persons believe that the ethical problems raised by creating the genetic material of life—including human life—should not be compounded by providing that such life can be “owned” by patent holders. See Brief on Behalf of Peoples Business Commission, 9-13. Others favor exploitation of this research under the patent system and suggest that the patent system might control public health risks. Yet others are skeptical of this claim and see the need for far more consideration of the relationship between patent law and genetic engineering.²³ Resolution of such disputes is precisely the type of task for which Congress, and not the judiciary, is equipped.

The difficult policy questions raised by extension of patent protection to this vast new field make it

60080, 60108, 60134 (1978). See also “Recombinant DNA: Accelerated Processing of Patent Applications for Inventions,” 42 Fed. Reg. 2712-2713 (1977), which provided for special procedures for processing applications “relating to recombinant DNA, including those that contribute to safety of research in the field” (*ibid.*). This regulation was suspended in part by “Recombinant DNA: Suspension of Accelerated Processing of Patent Applications for Recombinant DNA Research Inventions,” 42 Fed. Reg. 13147 (1977). See also Wade, *Major Relaxation on DNA Rules*, 205 Science 1238 (1979).

²³ See generally the comments submitted to the Director of NIH and collected in 2 Recombinant DNA Research, *Documents Relating To “NIH Guidelines For Research Involving Recombinant DNA Molecules,”* June 1976-November 1977, 3-17 DHEW Pub. No. (NIH) 78-1139 (National Institutes of Health, Public Health Service, 1978).

incumbent on the judiciary to proceed with great caution. As this Court held in *Parker v. Flook*, judicial approval of the extension of patent coverage to a new field requires “a clear and certain signal from Congress.” 437 U.S. at 596. The Court in *Flook* found no such signal to allow extension of patent coverage to the “modern business of developing programs for computers.” *Id.* at 595. The ethical, health, and economic problems posed by granting patent protection to living things are, if anything, more vexing than those posed by computer programs. And, as we shall now show, not only has there been no “clear and certain signal” from Congress authorizing patent coverage, there are persuasive indications that Congress has never intended to authorize the patentability of microorganisms or living things generally under 35 U.S.C. 101.

II. CONGRESS DID NOT INTEND TO INCLUDE LIVING THINGS THEMSELVES WITHIN THE SCOPE OF THE GENERAL PATENT LAWS

The text of the patent statutes reflects a congressional intent that living things themselves are not patentable under Section 101. That Section provides that a patent may issue to the inventor of a new and useful “manufacture, or composition of matter.” Sections 161-164 of the Patent Code expressly authorize the grant of patents on one carefully defined class of living things. These Sections, passed in 1930 as an amendment to the predecessor of Section 101 and known as the Plant Patent Act, afford patent protection to certain kinds of asexually-reproduced plants.

As thus amended by the Plant Patent Act, Rev. Stat. 4886, the predecessor of Section 101, read in pertinent part:

Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof, or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant, * * * may * * * obtain a patent therefor.

The very fact that Congress originally added these provisions to the predecessor of Section 101 strongly indicates a congressional understanding that the terms "manufacture, or composition of matter" did not extend to living things, for otherwise the new authorization for issuance of a patent to one "who has invented or discovered and asexually reproduced any distinct and new variety of plant * * *" would have been redundant (and perhaps would have had the effect of repealing patent authorization for other types of plants, although Congress treated the Act as an extension, rather than a contraction, of patent coverage).

Similarly, the Plant Variety Protection Act, 7 U.S.C. 2402(a), enacted in 1970, enlarged the class of protectable living things by authorizing patent-type protection for new types of sexually reproduced plants. This Act, too, would be redundant under the reading of Section 101 adopted by the court below, for under that reading living things already were

patentable as "manufacture[s], or composition[s] of matter." See *Platt v. Union Pacific R.R.*, 99 U.S. 48, 58 (1878); *Born v. Allen*, 291 F.2d 345, 351 (D.C. Cir. 1960). See also *United States v. Ruzicka*, 329 U.S. 287, 293 (1946). These specific and carefully delimited amendments—which the decision below would either render meaningless or contort into partial repealers of a comprehensive authorization for patents on living things²⁴—are thus strong evidence that the general subject matter definition in Section 101 does not include living things.²⁵ Cf. *Stonite Products Co. v. Melvin Lloyd Co.*, 315 U.S. 561 (1942); *Fourco Glass Co. v. Transmirra Corp.*, 353 U.S. 222, 228 (1957).²⁶

The legislative history of the plant patent statutes confirms this reading. Congress in the Plant Patent Act intended to extend patent protection for the first

²⁴ Indeed, the Plant Variety Protection Act provides more limited protection than the general patent law in several respects. Compare 35 U.S.C. 271 with 7 U.S.C. 2541; cf. 7 U.S.C. 2543 (farmers may save seed from plants grown from protected seeds for replanting or sale to other farmers).

²⁵ Similarly, designs are not included within the general definition of patentable subject matter in Section 101, but are specifically provided for in 35 U.S.C. 171.

²⁶ Judge Baldwin's concurrence focuses on the scope of the claims involved, and concludes that they define statutory subject matter because they do not seek to "preempt natural laws or phenomena" (Pet. App. 73a, 91a). But this analysis overlooks the fact that, regardless of the scope of the claims, the subject matter involved is a living organism—simply not the kind of discovery that the statute was designed to protect. Cf. *Flook*, *supra*, 437 U.S. at 592-593.

time beyond its previous limits. See *Application of Le Grice*, 301 F.2d 929, 939 (C.C.P.A. 1962). Both the House and Senate committees considering the bill reported that:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry * * *. The bill will remove the existing discrimination between plant developers and industrial inventors. [H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930)].²⁷

Appended to both the House and Senate Reports were letters from then Secretary of Agriculture Hyde, solicited by the respective committee chairmen, referring more specifically to the coverage of the pre-existing patent law:

The evident purpose of the bill is to encourage the improvement of some kinds of cultivated plants * * *. This purpose is sought to be accom-

²⁷ The theme that plant developers did not have the benefits of the patent system appears throughout the committee reports. Both the House and Senate reports pointed out that, "[t]o-day the plant breeder has no adequate financial incentive to enter upon his work. A new variety once it has left the hands of the breeder may be reproduced in unlimited quantity by all." H.R. Rep. No. 1129, *supra*, at 1; S. Rep. No. 315, *supra*, at 1. The Committees also noted that "there is no apparent difference * * * between the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter which are patentable under existing law." H.R. Rep. No. 1129, *supra*, at 7; S. Rep. No. 315, *supra*, at 7.

plished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inanimate nature. [H.R. Rep. No. 1129, *supra*, at Appendix A; S. Rep. No. 315, *supra*, at Appendix A.]

The Secretary's opinion on the existing law's scope, considered by Congress when it passed the Plant Patent Act, is entitled to substantial weight in statutory construction. See *New York Central R.R. v. Winfield*, 244 U.S. 147, 149-150 (1917); *United States v. Silk*, 331 U.S. 704, 710 n. 5 (1947); *Johnson v. Southern Pacific Co.*, 196 U.S. 1, 19-20 (1904). That weight is all the greater since Congress valued the Secretary's views on the need for new legislation and charged him with an important role in its administration. See H.R. Rep. No. 1129, *supra*, at 3; S. Rep. No. 315, *supra*, at 3.²⁸

²⁸ Thus the CCPA's disregard of Secretary Hyde's opinion concerning existing law, because Congress asked for his views only "on the proposed participation of his department in the *administration* of the new law" (Pet. App. 62a; emphasis in original) is wide of the mark. The court further erred in stating that "[t]here is no reason to attribute it [the Secretary's opinion] to Congress" (*ibid.*). The committees plainly found the Secretary's views significant; while they did not discuss in the committee reports his opinion on the existing law's subject matter coverage, they both referred to his letter in connection with other matters. H.R. Rep. No. 1129, *supra*, at 3, 6; S. Rep. No. 315, *supra*, at 3, 5. In view of their respect for the Secretary's interpretation of the proposed bill, and the fact that his understanding of the scope of existing law was nowhere challenged in the reports, the committees' failure to discuss his letter on the issue of coverage strongly indicates general agreement with his views

The principal House sponsor of the bill, Representative Purnell, held similar views. During House hearings, he concurred in the hope "that some day the patent law would be amended so as to give the man who developed new forms of plant or animal life an opportunity to control reproduction." *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 4 (1930).²⁹ Representative Purnell was confident that to amend the law to allow patents on living things would benefit the public. Some legislators did not share Purnell's optimism, but even opponents agreed that the new law provided patentability for living things that was not available under existing law. See, e.g., 72 Cong. Rec. 8391 (1930) (remarks of Rep. Stafford).³⁰

on the issue—especially since similar views are stated in the committee reports themselves (see n.27, *supra*).

Respondent Chakrabarty suggests that the Secretary's views should be disregarded because he was "not shown to have any expertise in the patent law" (Brief in Opposition 11). This comment assumes that the letter was written without consultation, which would be at least unusual for the formal expression of a federal department's views on pending legislation in a field of mutual concern to several departments. In any event, the Secretary had the advice of expert patent counsel, before writing his letter. See *Diener*, *supra*, note 13.

²⁹ The opinion was stated in what Rep. Purnell called a "splendid" letter containing the views of Chicago patent attorney, Col. Francis W. Parker, who had studied this issue. *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 4 (1930).

³⁰ Rep. Stafford at the beginning of House debate on the bill objected that the bill "is establishing a precedent to provide for a patent to those who develop a rare species of cattle or chickens." 72 Cong. Rec. 8391 (1930).

In 1970 Congress again evidenced its belief that living organisms were not covered by 35 U.S.C. 101, and that to afford them protection separate legislation was needed. The Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542, 7 U.S.C. 2321 *et seq.*, gave the Secretary of Agriculture authority to issue certificates of Plant Variety Protection, similar to patents, for new varieties of sexually-reproduced plants (Section 51, 7 U.S.C. 2421).³¹ Significantly, the statute expressly provides that bacteria are not entitled to plant variety protection (Section 42, 7 U.S.C. 2402). The legislative history does not explain the reason for this exclusion,³² but it cannot fairly be read as supporting the conclusion that the exemption was intended to preserve an assumed pre-existing patentability of bacteria under the general patent law.³³

³¹ The objection to including sexually reproduced plants under the 1930 Plant Patent Act had been that new varieties could never be reproduced true-to-type through seedlings. S. Rep. No. 315, *supra*, at 4; H.R. No. 1129, *supra*, at 4-5. But by 1970 it was generally recognized that new seed plant varieties could sometimes be reproduced true-to-type. See ABA Patent, Trademark and Copyright Law Section, 1968 *Committee Reports* 29 (1969).

³² As the court below suggested (Pet. App. 63a), the exclusion may simply have reflected congressional agreement with the result reached in *In re Arzberger*, 112 F.2d 834, 837 (C.C.P.A. 1940), in which the CCPA had recognized that "the characteristics of plants predominate in bacteria, and bacteria are usually scientifically classified as plants," but nevertheless affirmed the Board's refusal to issue a plant patent for certain bacteria.

³³ Nothing in *Arzberger* implies that the bacteria could have been patented under the general patent law. Instead, the court

Instead, the legislative history of the Plant Variety Protection Act unmistakably indicates that Congress was extending protection to articles not previously covered under the patent laws—*i.e.*, articles that were not within the terms of either the 1930 Act or 35 U.S.C. 101.³⁴ Thus, the House Report states (H.R. Rep. No. 91-1605, 91st Cong., 2d Sess. 1 (1970)):

Under patent law, protection is presently limited to those varieties of plants which reproduce asexually * * *. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans.

A similar statement appears in the Senate report, S. Rep. No. 91-1246, 91st Cong., 2d Sess. 3 (1970). Lack of coverage under the patent law for sexually reproduced plants was specifically brought to the Congress' attention by the Act's sponsors in the Senate and by the chairman of the Committee on Agriculture in the House during the debates on the bill. 116

quoted with approval the examiner's statement that the Plant Patent Act was not designed "to afford patent protection for bacteria" (112 F.2d at 836), suggesting that no such protection was otherwise available.

³⁴ Since the Plant Variety Protection Act covers similar subject matter, and indeed is fashioned after the Plant Patent Act, it must be construed together with the general patent laws. See *Northcross v. Memphis Board of Education*, 412 U.S. 427, 428 (1973); *Allen v. Grand Central Aircraft Co.*, 347 U.S. 535, 541 (1954).

Cong. Rec. 34680 (1970); 116 Cong. Rec. 40295 (1970). The same theme was repeatedly echoed by seed manufacturers, patent lawyers,³⁵ government officials, and congressmen during the hearings on the bill. *Plant Variety Protection: Hearings on H.R. 13424, etc., Before the Subcomm. on Departmental Operations of the House Comm. on Agriculture*, 91st Cong., 2d Sess. 6, 9, 21, 24, 25, 30, 33, 40, 43-44, 47, 51, 53 (1970). *Plant Variety Protection Act: Hearings on S. 3070 Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture and Forestry*, 91st Cong., 2d Sess. 48, 50, 68, 69 (1970). Moreover, the Act exempts "okra, celery, peppers, tomatoes, carrots, and cucumbers." 7 U.S.C. 2583. The reason for the exemption was that since food processing companies, the major developers of these plants, "do not produce new varieties for sale as such" there would be no purpose in affording them protection. S. Rep. 91-1246, *supra*, at 2. This rationale evidently assumes

³⁵ The resolutions passed by the ABA Patent Section favoring extension of the basic patent laws to cover sexually reproduced plants and microorganisms (see note 12, *supra*) are summarized in the testimony of Andrew Klein before the House Agriculture Committee. *Plant Variety Protection: Hearings on H.R. 13424, etc., Before the Subcomm. on Departmental Operations of the House Comm. on Agriculture*, 91st Cong., 2d Sess. 43 (1970). He noted, in both his oral and written presentation, that the ABA had supported one or more bills proposed by Senator McClellan (the chairman of the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee), "with respect to patent protection for micro-organisms" (*id.* at 43, 47). No hearings were held on the bills referred to by Mr. Klein.

these plants are not protected under the general patent laws.

The Court of Customs and Patent Appeals initially tried to avoid this legislative history. Its principal argument was that the history recited above should be ignored, for it "ascribe[s] to a preceding Congress an intent that the members of that Congress did not themselves state" (Pet. App. 51a). This notion that subsequent legislative history should be considered wholly irrelevant finds no support in the decisions of this Court. Careful use of such legislative history is always in order.³⁶

The views of the Congresses that amended Section 101 with the Plant Patent Act and added the Plant Variety Protection Act are particularly useful in discerning the scope of Section 101 for several reasons. They illuminate the meaning of the obscure but key words "manufacture, or composition of matter," terms which hardly define themselves. *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-381 (1969); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 274-275 (1974); *Califano v. Sanders*, 430 U.S. 99, 105-107 (1977). In addition, this legislative history was available to the Congress which in 1952 codified the patent laws in Title 35. Although the 1952 Congress

³⁶ In the primary case cited by the lower court (Pet. App. 51a) to support its disregard of legislative history, *United States v. Price*, 361 U.S. 304 (1960), this Court actually relied in part on subsequent legislative history to interpret a statute. *Id.* at 312-313. The Court simply refused to make inferences from that subsequent legislative history for which there was no basis. *Id.* at 313.

transferred the language covering plant patents from the general patent law (Rev. Stat. 4886, now 35 U.S.C. 101) to a separate section (35 U.S.C. 161 *et seq.*), thus directing its attention specifically to the plant provisions, it made no substantive changes in those provisions, nor any relevant changes in the scope of the general definition of patentable subject matter. Accordingly, the re-enactment of both the general definition and the specific extension constituted a ratification of the interpretation of the relation between those provisions reflected in the Plant Patent Act. The 1952 codification thus confirms that Congress intended to allow coverage for living things only as expressly provided under the Plant Patent Act. See *Douglas v. Seacoast Products, Inc.*, 431 U.S. 265, 278-279 (1977). Finally, as is implicit in the CCPA's failure to cite any other legislative history, this legislative history is the best, and only pertinent, history available—it was only on these occasions that Congress specifically focused on the question of the patentability of living things.

The lower court ultimately did consider the legislative history, and it offered two principal arguments in an effort to explain it away (Pet. App. 56a-61a). First it stated that Congress did not think it important that plants were alive, but only that they were within an agricultural (non-industrial) "field of endeavor" that required stimulation from the patent system (Pet. App. 56-59a). But the patent system from its beginning has been applied to inani-

mate invention in the field of agriculture.³⁷ What distinguishes newly created plants from agricultural machinery is that plants are alive.³⁸ This fact was recognized by both congressional committees considering the Plant Patent Act when they reported that:

There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful natural mineral. [H.R. Rep. No. 1129, *supra*, at 7; S. Rep. No. 315, *supra*, at 6.]

³⁷ See, e.g., *The Corn-Planter Patent*, 23 Wall. (90 U.S.) 181 (1874); *Acme Hay Harvesting Co. v. Martin*, 33 F. 249, 251 (Cir. Ct. N.D. Ill. 1888).

³⁸ This view was shared by many botanists and horticulturalists. Thus, David Fairchild, president of the American Genetic Association, wrote of his work creating new hybrid fruit:

The hybrid is made; let it take its course. It shall have to, since the Patent Laws of America will give me no assistance. Were they fair and designed to support invention in other fields than in those of mechanical things * * * I might awake some day, as inventors have, to find myself drawing a royalty from my Actinidia hybrid.

Fairchild, *The Fascination of Making A Plant Hybrid*, 18 J. of Heredity 49, 62 (1927). And Luther Burbank is quoted as having advocated patent law coverage for new plant varieties, as follows (72 Cong. Rec. 8392 (1930)):

* * * A man can patent a mousetrap or copyright a nasty song, but if he gives the world a new fruit that will add millions to the value of earth's annual harvests, he will be fortunate if he is rewarded by so much as having his name connected with the result * * *

See also Mole, *The Expanding Scientific Role of the Federal Government in the Nineteenth Century: The Patent Office As A Case Study*, 60 J. Pat. Off. Soc'y 328, 331-333, 340-341 (1978).

The CCPA also suggested that in 1930 Congress considered that plants were not patentable because they were thought to be a product of nature "unaffected by the hand of man," not because they were alive (Pet. App. 59a-60a).³⁹ This proposition overlooks the fact that Congress in the Plant Patent Act carefully distinguished between products of nature—plants found in their wild state and then cultivated—and products of man (aided, of course, by nature)—new plant varieties developed by experimenters like Luther Burbank through cross-pollination—and provided patent protection only to certain of the latter.⁴⁰

³⁹ Whatever the merits of this argument as applied to the 1930 Act, it clearly does not explain the 1970 Act. By 1970 numerous new plant varieties had been created using chemicals or radiation to change the genetic structure of naturally occurring plants. See, J. James, *Create New Flowers And Plants Indoors And Out* 116-117, 127-136 (1964); Emsweller, *Use of Colchicine in Plant Breeding*, in Brooklyn Botanic Garden, *Handbook on Breeding Ornamental Plants* 96-97 (1959); Singleton, et al., *Radiation Genetics and Crop Improvement*, in Brooklyn Botanic Garden, *supra*, at 98-100. These varieties are no more "products of nature" than is Chakrabarty's microorganism.

⁴⁰ Burbank's main work involved the production of new plant varieties by cross-pollination or hybridization. H. de Vries, *Plant-Breeding* 174 (1907); D. Jordan & V. Kellogg, *The Scientific Aspects Of Luther Burbank's Work* 4-7 (1909). This involved combining the desirable qualities of different strains within a species, or of different species, and the elimination of undesirable characteristics. De Vries, *supra*, at 174, 210. Burbank's method involved the deliberate transferring of the pollen from the flower of one plant to the stigma of the flower of another plant. W. S. Harwood, *New Creations in Plant Life* 25, 232-233 (1905). Burbank selected the best of the new plants resulting from a number of these crosses and

Thus Congress ultimately accepted the view that plants that are products of nature should remain unpatentable, and enacted the statute solely to extend patent protection to plants that are *not* products of nature, but had, theretofore, nevertheless been unpatentable solely because they are alive.

The plant legislation as originally introduced went so far as to cover even varieties of plants found in nature and then asexually reproduced.⁴¹ The Com-

propagated them. *De Vries, supra*, at 174. Burbank's was not the only work in plant genetics and breeding. X-rays had been used to change the genetic structure of barley and maize seeds prior to passage of the Plant Patent Act of 1930. See Singleton, *et al.*, *Radiation Genetics and Crop Improvement* in Brooklyn Botanic Garden, *Handbook On Breeding Ornamental Plants* 98 (1959). And as early as 1904 one researcher reported doubling chromosomes in plant roots using narcotics. Blakeslee and Avery, *Methods of Inducing Doubling of Chromosomes in Plants*, 28 J. of Heredity 393, 394 (1937). The discussion in the 1930 committee reports demonstrates that Congress was aware of the details of Burbank's work as well as of other research involving the creation of new plant varieties. H.R. Rep. No. 1129, *supra*, at 8; S. Rep. No. 315, *supra*, at 7. While Chakrabarty's research design and equipment is far more sophisticated, in concept the work of these early researchers is not different from Chakrabarty's (see Pet. App. 31a). The bacteria claimed by Chakrabarty are basically hybrid organisms.

⁴¹ The first Senate and House bills, which extended patent protection to "[a]ny person who has invented or discovered * * * any new and distinct variety of asexually reproduced plant," both contained the following proviso:

Provided: That the words "invented" and "discovered" * * * in regard to asexually reproduced plants, shall be interpreted to include invention and discovery in the sense of finding a thing already existing and reproducing

missioner of Patents opposed coverage of this kind of plant, but did support amending the predecessor of Section 101 to allow patents on plants that are the creation of man, not of nature. See *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 6 (1930). Such plants resulted, as he stated, "from human efforts", not from nature, but "the present patent law does not make it possible to grant patents" for them. *Id.* at 6. Congress agreed to this change; for the first time it made a limited class of living things patentable, but only where they were the product of man.

The lower court focused largely on a single decision and law review article antedating the Plant Patent Act: *Ex Parte Latimer*, 1889 Dec. Comm. Pat. 123, and Thorne, *Relation Of Patent Law To Natural Products*, 6 J. Pat. Off. Soc'y 23 (1923) (Pet. App. 59a-60a). The short answer to this constructed legislative history is that the actual legislative history of the Plant Patent Act contains no evidence of congressional awareness of either *Latimer* or the Thorne article: neither is mentioned, let alone relied on. Even if Congress had been aware of them, however, there is nothing in either that suggests that new plant varieties of the type created by Burbank through cross-pollination should be treated as "products of nature". In *Ex Parte Latimer* the Commissioner refused a

the same as well as in the sense of creating. [S. 3530, 71st Cong., 2d Sess., amending Rev. Stat. 4886 (1930); H.R. 9765, 71st Cong., 2d Sess., amending Rev. Stat. 4886 (1930); R. Allyn, *The First Plant Patents* 60 (1934).]

patent on natural fiber taken from the needle of a tree (*Pinus australis*), the extraction of which "natural product" involved "little more than one who gathers the pebbles along the seashore, where the forces of nature have placed them." Dec. Comm. Pat. at 126-127. The decision hardly can be said to imply that new plant varieties created by plant breeders are unpatentable because they are products of nature. Thorne, relying mostly on *Latimer*, confines his "product of nature" discussion to plants "discovered and propagated by scientific means" without saying whether this "discovery" is limited to finding a new plant growing in nature or includes varieties created by horticulturalists. See Thorne, *supra*, at 23; also *id.* at 25, 27-28.

Finally, the court below cited as a reason for passage of the Plant Patent Act the need to overcome the difficulty of describing a plant in a written document (Pet. App. 62a). But while this theory explains the amendment (now 35 U.S.C. 162) to Section 4888 of the Revised Statutes (now 35 U.S.C. 112),⁴² which requires a written description of the invention, it does not explain why Congress found it necessary also

⁴² The amendment read as follows:

Section 4888 of the Revised Statutes, as amended (U.S.C. title 35, sec. 33), is amended by adding at the end thereof the following sentence: "No plant patent shall be declared invalid on the ground of noncompliance with this section if the description is made as complete as is reasonably possible."

to amend Rev. Stat. 4886 (now 35 U.S.C. 101) to include asexually reproduced plants as patentable subject matter. Moreover, difficulty of description was not mentioned in either the House or Senate report as a reason for passing the bill. See H.R. Rep. No. 1129, *supra*, at 1-4; S. Rep. No. 315, *supra*, at 1-3.⁴³

There is, in sum, no plausible indication in the legislative history of any basis for enactment of the Plant Patent Act independent of the repeatedly suggested premise that existing patent law did not authorize the patenting of living things.

III. THE OTHER REASONS OFFERED BY THE COURT BELOW IN SUPPORT OF ITS DECISION ARE UNPERSUASIVE

The court below stated that Congress could not rationally have intended to prohibit the patenting of living things since patents have long been allowed on processes that use living things (Pet. App. 48a-49a; 67a-68a). See *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453, 455-456 (2d Cir.), cert. denied, 209 U.S. 548 (1908); *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628, 630-631, (S.D.

⁴³ The only place in the legislative history where the point was discussed was in the memorandum of Commissioner Robertson in the record of the House hearings. See *Hearings on H.R. 11372, supra*, at 7. It was there mentioned not as a reason for passing the bill, but because the Commissioner thought that if the patent law was amended to make plants patentable subject matter, a further amendment would be needed to relieve plant inventors of the strict specification requirements of Rev. Stat. 4888. *Ibid.*

N.Y. 1930); *Guaranty Trust Company v. Union Solvent Corporation*, 54 F.2d 400 (D.Del. 1931). But it hardly follows that because a process is patentable, every component of that process also qualifies for a patent. Thus, a new and useful process using common, inanimate components in an original way may qualify for a patent without each of those inanimate components themselves being patentable. Compare *Application of Deutsch*, 553 F.2d 689, 692-693 (C.C.P.A. 1977), with *Application of Waldbaum*, 559 F.2d 611, 616-617 (C.C.P.A. 1977). Similarly, a scientific principle or formula, itself not patentable, may provide the theoretical basis for a patentable process. See *Parker v. Flook*, *supra*, 437 U.S. at 591; *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1939). Accordingly, the fact that a patent is allowed on a new and useful process incorporating a living organism does not suggest that the organism itself is patentable subject matter.⁴⁴ Similarly, a method of achieving an unpatentable end product may be patentable. See *Application of Toma*, 575 F.2d 872 (C.C.P.A. 1978) (method of using computer to translate text from one language to another).

The CCPA also stated that the Patent Office has regularly granted patents on living things and

⁴⁴ The court's related proposition that living things are useful, are based on chemistry and thus should receive patent protection (Pet. App. 44a) is no more persuasive. Utility does not mean patentability. *Parker v. Flook*, *supra*. And whether or not life is, as the CCPA would have it, "largely chemistry" (Pet. App. 44a), the decision to extend the patent laws from the nonliving to the living is a policy judgment for Congress to make (see *supra*, pages 12-21).

that administrative practice supports the court's reading of Section 101 (Pet. App. 65a-67a). The policy of the Patent Office, however, is that living things are not themselves patentable, and neither the Commissioner nor the Board of Appeals has deviated from that policy. The court merely cited patents granted by some of the Patent Office's roughly one thousand examiners⁴⁵ that the court asserts were issued on living things (Pet. App. 66a-67a).⁴⁶ These grants have minimal precedential significance, since they were only isolated actions of lower level employees, made on applications neither contested nor reviewed. See *Fishgold v. Sullivan Drydock & Repair Corp.*, 328 U.S. 275, 290 (1946); *SEC v. Sterling Precision Corp.*, 393 F.2d 214, 220 (2d Cir. 1968) (Friendly, J.). Moreover, there is no evidence whatever that Congress was aware of these patents or that the examiners who approved them took part in the legis-

⁴⁵ The Patent and Trademark Office granted 70,320 patents in FY 1978. A staff of 1,064 professional employees worked there at the time, mostly in the patent examining corps. *Commissioner Of Patents And Trademarks, Annual Report FY 1978*, 12, 30 (1979).

⁴⁶ Some of the patents cited by the court claim a virus, which some scientists consider to be without life (Pet. App. 66a-67a, Nos. 5, 8). See Weaver, *The Cancer Puzzle*, 150 Nat'l Geographic 396, 397 (Sept. 1976); Gore, *The Awesome Worlds Within a Cell*, 150 Nat'l Geographic 355, 386 (Sept. 1976). With respect to others the invention apparently resides in nonliving material which is a part of the claim (see Pet. App. 66a, No. 4; 67a, No. 8). One other involves bird seed that is treated at such a high temperature (170-180° F) that the seed is likely dead (Pet. App. 66a, No. 6).

lative process of amendment or codification of the patent laws. See *Helvering v. Hallock*, 309 U.S. 106, 120 (1940); *Zuber v. Allen*, 396 U.S. 168, 192-193 (1969).⁴⁷ The court thus erred in relying on these few aberrant patent grants by individual examiners as persuasive evidence of administrative interpretation of the patent laws, rather than relying on the Commissioner's considered interpretation of the statute he is charged with administering. *Udall v. Tallman*, 380 U.S. 1, 4 (1965).⁴⁸

⁴⁷ The sole possible exception is the 1873 Pasteur patent on yeast (Pet. App. 65a), which P. J. Federico, a principal draftsman of the Patent Act of 1952 (*id.* at 42a n.11), had noted was unique as to subject matter and probably wrong. Federico, *Louis Pasteur's Patents*, 86 Science 327 (1937).

⁴⁸ The CCPA also noted as a "matter of general interest" that the assignee of Chakrabarty's invention had been granted a British patent on the microorganism itself (Pet. App. 33a n.9). We have been advised by the British Patent Office that the claim was granted by the examiner there, but was not reviewed by the appeals board or by higher authority and was not subsequently challenged. We are further advised that the present practice on the granting of such patents in England is uncertain. See, e.g., *American Cyanamid Company (Dann's) Patent*, 1971 Pat. Cas. 425, 448 (Lords), where Lord Wilberforce commented: "The priceless strain, being something living, found in nature, cannot be patented * * *." In any event, it is settled that foreign practice has no bearing on the interpretation of the United States patent law. See *Application of Larsen*, 292 F.2d 531 (C.C.P.A. 1961), and cases cited therein.

CONCLUSION

For the foregoing reasons, the judgments of the Court of Customs and Patent Appeals should be reversed.

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JANUARY 1980

JAN 28 1980

FREDERICK RODAN, JR., CLERK

IN THE
Supreme Court of the United States
OCTOBER TERM, 1979

No. 79-136

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, *Petitioner*

v.

ANANDA M. CHAKRABARTY, *Respondent*

On Writ of Certiorari to the United States
Court of Customs and Patent Appeals

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1979

No. 79-136

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, *Petitioner*

v.

ANANDA M. CHAKRABARTY, *Respondent*

On Writ of Certiorari to the United States
Court of Customs and Patent Appeals

BRIEF FOR THE RESPONDENT

QUESTION PRESENTED

Whether patent claims to a concededly novel and unobvious bacterium, made by man for treatment of oil spills, should be denied solely because the bacterium is alive.

STATEMENT

Certiorari initially was granted as to two separate and independent patent applications having in common only that claims to bacteria had been rejected by the Board of Appeals of the United States Patent and Trademark Office (hereafter "Patent Office" or "PTO") because the bacteria are alive. Both rejections were reversed by the United States Court of Customs and Patent Appeals (hereafter "the Court below" or "CCPA").

The Involved Technology

Otherwise, the two inventions are quite different. Bergy et al discovered and isolated from Arizona soil a biologically pure species of bacterium or actinomycete called "*Streptomyces vellosus*," found to be useful in production of a previously known antibiotic called "lincomycin." Bergy's claims to the process of production of lincomycin by use of that bacterium were allowed by the Patent Examiner and never rejected because of the living nature of the bacterium. Only the claim to the bacterium itself was the subject of appeal. After certiorari was granted, but before the Government's brief was filed, that claim was cancelled, and Bergy's motion to dismiss for mootness was filed. That motion was granted January 14, 1980.

Chakrabarty worked in the field of cellular genetic engineering, sometimes called microbial genetics. His engineered bacterium, not previously existing in nature, functions to solve one of man's practical needs, getting rid of oil spills.

Oil is a mixture of several component hydrocarbon compounds. Since any given strain of known bacteria degrades only a particular component, prior biological control of oil spills involved use of a mixture of bacterial strains, each specific to a different oil component. Unfortunately, these bacterial strains do not thrive under the same conditions. As a result, when a mixture of bacterial strains is deposited on an oil spill, the bulk of the oil remains unattacked by the bacteria and is free to spread or sink, with time.

Prior to this invention Chakrabarty and Gunsalus discovered that the degradation abilities of certain bacteria are controlled by what is called a "plasmid." A plasmid is an extrachromosomal element; that is, it is a hereditary unit, physically separate from the chromosome of the cell. Chakrabarty and Gunsalus discovered plasmids in two different strains of bacteria, which were each capable of degrading a different oil component, specifically camphor and octane. However, their attempts stably to combine the respective plasmids in a single microorganism were unsuccessful.

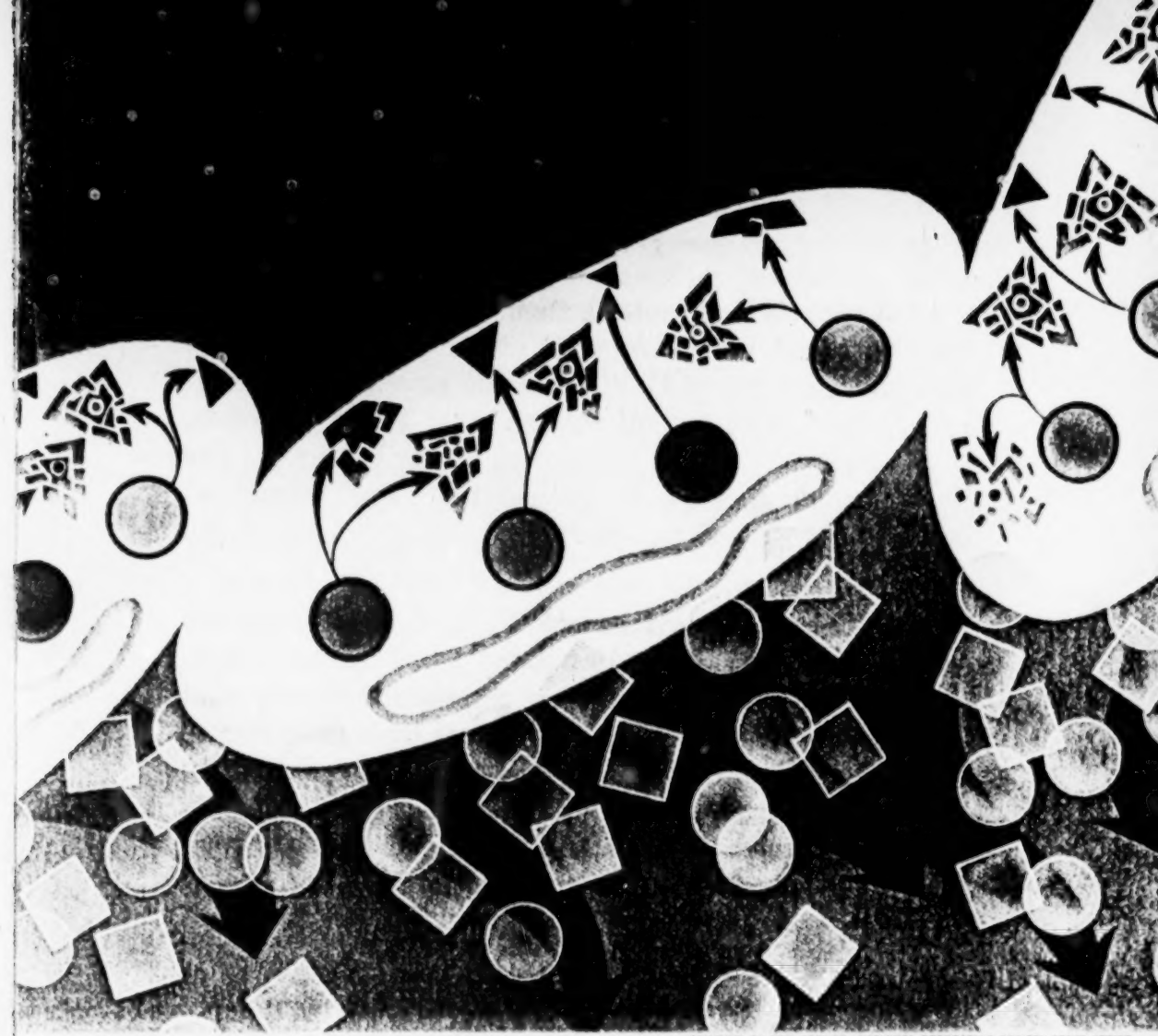
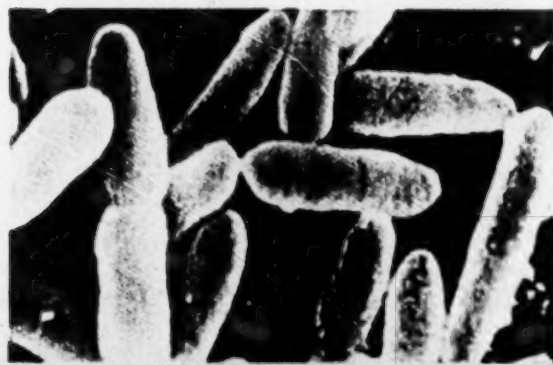
In the work represented by the patent application involved herein, Chakrabarty discovered that plasmids capable of degrading the same two oil components, and plasmids capable of degrading two additional components, could be transmitted to and maintained stably in a single bacterium. His discovery is explained and illustrated in the following excerpt from the *National Geographic* article on "The New Biology", September 1976, Volume 150, No. 3, page 355, at 374-375 (reprinted by permission).



Breeding a superbug to attack oil spills

From cloudy to clear, the two vials held by Dr. Ananda M. Chakrabarty (above) of General Electric's research center demonstrate genetically engineered bacteria's gluttonous appetite for oil. By combining four strains of oil-eating bacteria, Dr. Chakrabarty has created a corps of ultras-small scavengers (below) that one day may devour oil spills.

Natural bacteria aid in digestion and break down human wastes; perhaps a whole host of altered strains could help clean up our messy planet.



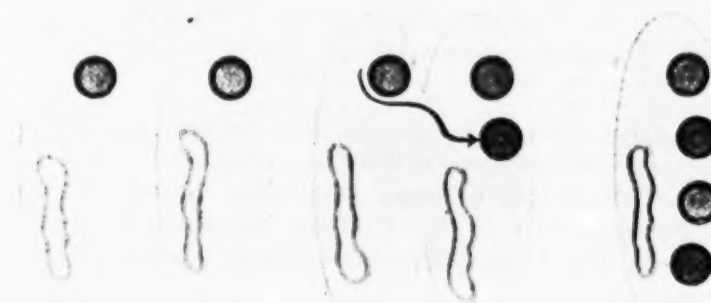
PAINTING BY NED SEIDLER, NATIONAL GEOGRAPHIC SOCIETY STAFF ARTIST

Feasting on oily waters, the superstrain *Pseudomonas* demonstrates its talents in the diagram above. Each of the four strains digests particular hydrocarbons of crude oil. But like a crowd jostling around a bargain counter, they function inefficiently. By taking a plasmid of one strain

(below, green circle in diagram) that attacks specific hydrocarbons and then adding the plasmid of a different strain (red circle), a double-barreled strain is produced. Two more specialized plasmids are added (blue and orange circles). The completed bacteria are activated with ultraviolet radiation, so that they can reproduce with all four plasmids intact. The bacteria are now ready to feast.

In a mixture of oily water the bacteria digest their specified hydrocarbons (above, color-coded triangles in diagram)—up to two-thirds of the total oil present.

What remain are mostly the useful by-products water and carbon dioxide (circles and squares), and bacterial protein.



Chakrabarty's invention, then, is a new microorganism, made by him, composed of an identified bacterium having a plurality of plasmids providing for degradation of different oil components. These plasmids, if not naturally stable within the single bacterium (as the plasmids specific to the camphor and octane oil components were not), are made stable by fusion (App. 46 and 47).¹

The Chakrabarty man-made bacterium not only has the capability of degrading multiple oil components, but it actually degrades the oil more effectively and rapidly than a mixture of individual, naturally-occurring bacteria. Chakrabarty's bacterium breaks down or degrades multiple components of the oil into simpler substances which serve as food for the bacterium. Ultimately, the bacterium becomes food for aquatic life. Thereby, noxious oil is effectively converted into a useful link in the food cycle of the sea.

Patent Office Consideration

In the Patent Office, claims to a floatable carrier inoculated with Chakrabarty's engineered bacterium have been allowed. One such claim (number 30) is as follows:

"An inoculated medium for the degradation of liquid hydrocarbon substrate material floating on water, said inoculated medium comprising a carrier material able to float on water and bacteria from the genus *Pseudomonas* carried thereby, at

¹ Chakrabarty's application is duplicated in the joint Appendix, cited as "App. —", the darker brown volume, pages 40-77. The rejected and allowed claims are at pages 87-88. The lighter tan volume contains the Appendix to the Petition, hereinafter cited as "Pet. App. —". The Appendix to Chakrabarty's brief is cited as "R. App. —."

least some of said bacteria each containing at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway and said carrier material being able to absorb said hydrocarbon material."²

In essence, this claim covers a floatable material, such as straw (specifically recited in allowed claim 31), carrying the bacterium of the rejected claims. Claims to Chakrabarty's technique of making incompatible plasmids compatible were also allowed. Accordingly, in the normal course of events, a patent will issue on the involved patent application, containing at least claims to the bacterium on a floatable carrier, and claims to the method of making the bacterium (Opinion below, Pet. App. 2a). This appeal, therefore, is concerned not with whether a patent should issue, but rather with whether claims to Chakrabarty's bacterium, alone, should be allowed.

Claims to the bacterium itself, were finally rejected by the Patent Examiner as directed to "a thing occurring in nature" (Pet. App. 165a-167a). On appeal a three-man panel of the Board of Appeals of the Patent Office reversed as to this rejection, finding that the claimed bacterium in fact did not occur naturally but

² While this (and other) claims were allowed by the Patent Examiner and not rejected by the Board of Appeals, the PTO Solicitor suggested in briefing before the CCPA that this position might be erroneous and would be reconsidered upon remand to the Examiner following the appellate process:

"Consideration has also been given to appellant's observation (Br-22) that it 'is strange indeed that claims for the bacterium on a carrier are allowable, while claims to the organism are not'. In light of the decision of the Board in *In re Bergy*, fn. 1 *supra*, there may be an anomaly, which can be rectified on return of this case to the Office." Commissioner's Brief in Patent Appeal No. 77-535.

rather was manufactured by Chakrabarty. (Pet. App. 159a, 163a). Nevertheless, the panel generated a new ground of rejection not made by the Examiner nor supported by authority. The new ground was based on the living nature of the claimed bacterium. (Pet. App. 159a-164a) ³.

Initial CCPA Consideration

The Court of Customs and Patent Appeals reversed, holding that claims to a bacterium are not excluded from patenting because of its living nature. *Application of Chakrabarty*, 571 F.2d 40 (CCPA 1978) (Pet. App. 142a-148a). That court's earlier holding in *Application of Bergy*, 563 F.2d 1031 (1977) (Pet. App. 106a-121a) was stated to be controlling.⁴

CCPA Reconsideration

This Court granted certiorari in *Bergy*, vacated the ruling of the CCPA therein, and remanded for further consideration in light of *Parker v. Flook*, 437 U.S.

³ The Board's opinion characterizes the Examiner as having rejected the claims because the bacteria are "alive". As the CCPA pointed out, this just is not true (Pet. App. 35a). The Court's reference to the "Answer" is to the "Examiner's Answer" to Chakrabarty's brief on appeal. That Answer responded to allegations in the brief that Chakrabarty's living bacteria contrasted with the living bacteria found unpatentable by this Court in *Funk Bros. v. Kalo Co.*, 333 U.S. 127 (1948). The Answer did not reject because Chakrabarty's bacteria are alive.

⁴ Chakrabarty's application was decided by the Board before *Bergy*'s and the rationale of the Board's majority opinion in *Bergy* (a different panel decided *Bergy*) was essentially copied from the Chakrabarty Board decision. However, the *Bergy* appeal to the CCPA was heard and decided before Chakrabarty, because of delay attending Chakrabarty's petition for reconsideration by the Board of Appeals.

584 (1978). Though a petition for certiorari was filed by the Government in *Chakrabarty*, it was not ruled upon by this Court. Rather, the petition was dismissed by stipulation, after the CCPA vacated its *Chakrabarty* ruling, for reconsideration of this case together with *Bergy*.

After briefing and argument of the significance of *Flook*, the CCPA affirmed its earlier judgments both in *Bergy* and *Chakrabarty* (Pet. App. 1a-70a), holding that the living nature of the claimed bacteria does not disqualify them from patent protection under 35 U.S.C. 101. More particularly, each bacterium was held to be either a "manufacture" or a "composition of matter" under that statute.

One result of the CCPA reconsideration was the change of a dissenting vote (Pet. App. 152a) on initial decision, to concurrence on reconsideration. Judge Baldwin, after careful consideration of this Court's opinion in *Flook*, and precedents therein cited, wrote a concurring opinion based on those precedents (Pet. App. 71a-94a).

Judge Miller dissented on the basis that the PTO had no authority to grant patents on living subject matter other than plants. His thesis was that passage of the Plant Patent Act by Congress in 1930 showed that previous Congresses, in establishing the classes of patentable subject matter, had not intended to allow patents for any living things.

The majority opinion below thoroughly considered *Parker v. Flook*, and its relation to this case, including the caution expressed as to areas of patentability "wholly unforeseen by Congress" 437 U.S. at 596 (Pet.

App. 20a-26a, 40a-49a). These and other considerations will be developed in the Argument section of this brief.

Petition for certiorari was applied for jointly in both *Bergy* and *Chakrabarty* and was granted on October 29, 1979. Upon cancellation of the Bergy claim to the bacterium,⁵ this Court granted the Bergy motion to dismiss for mootness, also vacating the decision below as to *Bergy*, on January 14, 1980.

SUMMARY OF ARGUMENT

Keystone of the Government's position is the allegation that patenting Chakrabarty's man-made bacterium would amount to extension of the patent laws into new areas. Apart from "occasional, aberrant decisions by individual Patent Office Examiners", the Patent Office, specifically the Commissioner and the Board of Appeals, are said to have consistently interpreted the relevant statute to foreclose this type of patent.

These unsupported contentions are demonstrably false.

Patents considered by this and other courts have been issued on living things, including bacteria. In fact, so many have issued that official Patent Office specific subclasses have been established for collection of these patents. Search of these subclasses and other sources, have located many, many patents to living

⁵ Contrary to the Solicitor General's response to the Bergy motion, it is understood that the Bergy application was not abandoned. Claims to the method of use of the Bergy bacterium remain allowed and the application presumably will be granted.

things. Included are ones in which the Board of Appeals has reversed an Examiner's rejection, thereby causing issuance of the patents. Indeed, a Commissioner of Patents has informed Congress that "cultures", which are living microorganisms, are patentable.

Following this consistent policy, the Examiner below allowed claims to Chakrabarty's bacteria, when inoculated onto a floatable carrier, specifically, straw. Here there is no extension of patent protection, but rather a belated attempt by the Government to reverse a long-established policy.

Chakrabarty's invention was not made by use of "recombinant DNA" techniques; misleading arguments concerning those techniques have no direct relevancy here.

The statutory history of the Plant Patent Act and the Plant Variety Protection Act are not significant evidence of the intent of the much earlier Congresses which established the statutory classes of invention. This Court has cautioned against such weak indications. Much more likely than the unexpressed purpose for which the Government contends, is that plants were not patentable because they are products of nature, a long-recognized rejection. Chakrabarty's invention, however, is admittedly not a product of nature. It is within the statutory classes of invention, as the Board of Appeals expressly below, and the Government impliedly here, recognize.

The living nature of Chakrabarty's invention should not foreclose patent protection for it. Rather, the incentive of the patent system should remain available for useful inventions, whether living or dead.

ARGUMENT

I. THE GOVERNMENT SEEKS BY THIS CASE TO REVERSE A LONG-STANDING POLICY OF GRANTING PATENTS ON LIVING THINGS

The keystone of the Government's position is that the issuance of claims to Chakrabarty's bacterium would represent an extension of patent protection into an area previously not considered patentable (Br. 9, 10, 12-16, 37-40).⁶ Without any supporting evidence, it is alleged that the policy of the Patent Office always has been to refuse patents on living things (Br. 10, 39-40). This allegation is demonstrably false.

Previous Patent Office policy has been to grant patents on living things, and specifically on bacteria. That policy is demonstrated (A) by issuance of patents considered by this and other courts, (B) by official classifications of issued patents, (C) by the absence of policy statements to the contrary, and (D) by the many issued patents found in a limited search of Patent Office records.

A. Court-Considered Patents To Living Things

This Court considered a patent to a mixture of living bacteria in *Funk Bros. Co. v. Kalo Co.*, 333 U.S. 127 (1948).⁷ Bond Patent No. 2,200,532, issued May 14, 1940 contained claims to bacteria useful in cultivation

⁶ As the CCPA points out, a patent will issue on the technology of the Chakrabarty invention, whichever way this Court decides the issue before the Court (Pet. App. 2a).

⁷ This case is ignored by the Government's brief, even though it was both cited and quoted in *Parker v. Flook*, 437 U.S. 584, 591 (1978), the decision this Court directed the CCPA to consider in connection with *Bergy* (438 U.S. 907).

of leguminous plants. No one in either the Patent Office or in the courts ever contended that the living nature of Bond's bacteria made them unpatentable.

Bond was interested in producing a mixture of different bacteria species which would respectively infect the roots of different types of leguminous plants. These different species assisted those types of plants to take nitrogen from the air and convert it into organic nitrogenous compounds, necessary to the plants' growth. Because no one species was effective for all types of leguminous plants, a mixture was necessary. However, it had previously been thought that the various species were mutually inhibitory, so as to reduce each other's efficiency. Bond found that this was not true as to some strains of these species. He claimed mutually non-inhibitive strains of the different bacterial species.

This Court held that Bond's discovery was of a natural phenomenon:

"Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable." 333 U.S. at 131.⁸

⁸ In contrast with Bond's mixture of different bacteria, Chakrabarty's invention is a single bacterium provided with additional characteristics, so that it can degrade a plurality of components of oil. The bacterium therefore performs differently to accomplish a new and better result. Compare with the reverse statements as to Bond's bacterial mixture at 333 U.S. 131:

"Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no

Beyond that discovery, it was held that Bond had done no more than mix the bacteria together. That "simple step" was found not to be the "product of invention". 333 U.S. at 132. In modern parlance (since the 1952 enactment of the present Patent Code), what Bond did would have been obvious to the man of ordinary skill in the art (35 U.S.C. 103). (This interpretation is the same one reached by the Board of Appeals below, Pet. App. 159a, 162a-163a, and by the Government in its initial brief to the CCPA, red cover, page 19.)

To repeat, this Court applied the same criteria of patentability to Bond's bacteria as it applies to inanimate inventions. Neither here nor in the courts below was patentability questioned because the bacteria was alive. Of course, the Patent Office had not held the claims unpatentable on that basis. It had granted the patent on living subject matter, which, like Chakrabarty's invention, are bacteria.

This Court considered another patent granted by the Patent Office on living subject matter, in *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931). Involved was Brogden et al. Patent No. 1,529,461 issued March 10, 1925. The claims defined fresh fruit whose skin carried a thin borax coating to resist blue mold decay of the fruit. Neither in the Patent Office nor in the courts was it contended that the living nature of the fruit made the claims unpatentable. This Court reversed a validity holding of the product claims on the basis that the fruit was not a "manufacture" within

change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning."

the meaning of Section 3i of Title 35 (Rev. Stat. 4886). The borax addition was held not to provide a new or distinctive form, quality or property to the raw fruit. Nor was there any change in the name, appearance or general character of the fruit.

"It remains a fresh orange fit only for the same beneficial uses as theretofore." 283 U.S. at 12.

In contrast, Chakrabarty's bacterium is wholly different from its natural ancestor. It is capable of degrading not just one, but a plurality of different components of spilled oil. It has added plasmids not characteristic of the "raw" product. The *American Fruit* tests qualify Chakrabarty's bacterium as a manufacture.

The Patent Office has also granted patents for mushroom spawn, which, of course, are alive. One such patent, Sinden No. 1,869,517, granted August 2, 1932, was held valid and infringed in *Pennsylvania Research Corp. v. Lescarboursa Spawn Co.*, 29 F. Supp. 340 (E.D. Pa. 1939). No suggestion that the living nature of the claimed subject matter made it unpatentable appears in the opinion.

Living subject matter was also involved in *Guaranty Trust Co. of New York v. Union Solvents Corp.*, 54 F.2d 400 (D. Del. 1931), *aff'd* on lower court opinion at 61 F.2d 1041 (3d Cir. 1932), *cert. denied* 288 U.S. 614 (1933). Weizmann, the inventor of Patent No. 1,315,585, issued September 9, 1919, had found that certain bacteria "found in soil and cereals" (page 1, lines 46-47), and therefore old in nature, could be used to make acetone and methyl alcohol. Only process claims to the method of making those materials, using the "found" bacteria, were issued. One of the defenses

rejected by the District Court in finding the patent valid and infringed, was that the life process of a living organism is unpatentable.⁹

B. Official Patent Office Classifications of Issued Patents On Living Subject Matter

The Patent Office has granted so many patents on live subject matter that it has established official subclasses of such patents, based on the inventions claimed therein. These subclasses facilitate novelty investigations both by Patent Examiners and the general public. For instance, Class 424 is entitled "Drug, Bio-Affecting and Body Treating Compositions". The official "Classification Definitions" for Class 424 say:

"Class 424 provides for compositions containing microorganisms, either alive, dead or attenuated;" (page 424-6).

Class 424 contains a Subclass 93 entitled:

"Whole Live Microorganism or Virus Containing".

The January 1979 subclass list of Class 195 "Chemistry, Fermentation" contained a Subclass 53 entitled:

"Ferment-Containing Products . . . , Living fungi-containing".

Class 195 was replaced in July 1979 by Class 435 "Chemistry: Molecular Biology and Microbiology". Subclass 235 of that class is for "Viruses", etc., and

⁹ To the same effect are *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 Fed. 453, 458 (2d Cir. 1908), *cert. denied* 209 U.S. 548 (1908), cited with approval by this Court in *Funk Bros. Co. v. Kalo Co.*, *supra*, 333 U.S. at 130; *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934), *cert. denied* 293 U.S. 576 (1934); *Ex parte Prescott*, 19 U.S.P.Q. 178 (P.O. Bd. App. 1932).

Subclass 243 for "Microorganism Per Se", etc. The official Class Definitions contain a section titled "II. Classification Lines With Other Classes". Under that heading appears the following:

"Class 424, Drug, Bio-Affecting and Body Treating Compositions, for a process of treating the living body with a microorganism or enzyme and the compositions therefor which may contain a live microorganism, co-enzyme, or enzyme . . . See especially . . . Subclass 93 for a composition including whole live microorganism or virus . . . Class 435 provides for . . . the virus or microorganism per se . . ." (page 435-1 - 4).

Certainly, these subclasses would not have been established and defined by Patent Office officials unless patents had been granted to be placed in the subclasses.

C. Official Expressions Of Patent Office Policy Identify Characteristics Other Than Life As Making Subjects Non-Statutory

The policy of the Patent Office is stated in the Rules and, since 1949, detailed in the official "Manual of Patent Examining Procedure". Both are silent as to living things, though the Manual lists the types of subject matter not considered by the Office to be within the ambit of 35 U.S.C. 101, as "Printed Matter", "Naturally Occurring Article", "Method of Doing Business" and "Scientific Principle".¹⁰ As noted in the Statement above (page 7), the Examiner rejected the

¹⁰ A copy of the indicated portion of the official Manual is attached in Respondent's Appendix (R. App. 1a). Hereafter in this Brief, reference to Respondent's Appendix will indicate that the material in question is at the indicated location in the Appendix.

claims here in issue as directed to a naturally occurring article, an officially recognized disqualification. Of course they are not, because the plural plasmid, plural component eating bacterium did not occur in nature, until Chakrabarty made it. The Board (Pet. App. 163a) agreed that was so. The Government does not contend otherwise.

If there had been a Patent Office policy to reject patents on living things, it would have been expressed with these other non-statutory exclusions in the Manual. It is not, nor has it ever been.

D. Searches Through These And Other Subclasses And Other Sources Have Identified Many Patents Claiming Live Subject Matter

Subclass 93 of Class 424, the "live microorganism" subclass, contains 138 patents. The first patent in the subclass, No. 952,418, was issued in 1910. It claims a living microorganism, such as lactic acid bacillus, mixed with cocoa or chocolate. The claimed utility is as a food product.

In addition to Subclass 93, we have conducted searches through other subclasses of Class 424 and through various subclasses of Class 435. Through those and other sources we have collected over 60 issued patents (R. App. 16a-18a) claiming living subject matter, mostly bacteria. These searches were made in response to the Government's contrived contention that Patent Office policy always has been not to grant patents on living things and that the few prior patents referred to in the CCPA opinion (Pet. App. 66a, 67a) are mere aberrations of some of the 1000 plus Examiners of the Patent Office, but not of the Commissioner or the Board of Appeals (Br. 38-40). Here are no mere

aberrations. Here is evidence of a consistent Patent Office policy, a policy the Government now seeks to change by this case.

Among these 60+ patents, we noted particularly that the Board of Appeals (including Mr. Magil, later a member of the *Chakrabarty* Board) reversed an Examiner's rejection of claims to living bacteria. This rejection was that the claims were for a discovery of nature, citing *Funk Bros. Co. v. Kalo Co.*, *supra*, 333 U.S. 127 (1948). The Board reversed this rejection, stating agreement with the applicant's characterization of his invention as the "nonobvious manipulation, utilization or application of known things to produce a utilitarian tangible composition of matter." The Board's opinion, published with the entire prosecution history of that patent (Farr Patent No. 3,420,742, January 7, 1969, R. App. 2a), also contained the following:

"We note that the patents cited in the Examiner's action, Paper No. 4, contain claims to cultures of bacteria. Attention is also directed to *In re Davis et al.*, 49 CCPA 1196; 305 F.2d 501 . . . which presented claims to vaccines containing both live and dead antigens of either viral or bacterial origin."¹¹ (R. App. 6a)

The patents referred to by the Board are Reichel et al. 1,957,555, May 8, 1934; and Nordsiek 2,121,442, June 21, 1938. The former claims a stabilized bacterium; the latter, a mixture of two bacteria.

¹¹ The Patent Office reconsidered this Farr patent through Farr's application for reissue. Claims to the bacteria were reissued in Reissue Patent No. 28,488 on July 22, 1975.

Contrary to the Government's unsupported allegation, the Board, like the Examiners whose rejections they review, has interpreted the statutes to allow patents on living microorganisms.

A later patent Morimoto et al. No. 3,642,982, patented February 15, 1972 (R. App. 9a), not only claims "living bacteria", the title was change by Examiner's amendment to be:

"The Utilization of Living Bacteria as Insecticides."

The claims of the last patent recite a carrier, specifically an insecticidal carrier, e.g.:

"1. An insecticidal composition containing living bacteria consisting essentially of an inert insecticidal carrier and *Serratia piscatorum* ATCC No. 17999 or *Streptococcus faecalis* ATCC Nos. 15335, 14336 and 19000, the living bacterium being present in an amount of 0.05 to 5 weight percent."

Claim 1 of Morimoto claims "living bacteria", even though the living bacteria are claimed in combination with a carrier. In similar fashion, claims allowed to Chakrabarty claim his bacterium with a carrier. See above, pages 6-7.

Macpherson et al. Patent No. 3,228,840, January 11, 1966, similarly claims a hamster cell line in a nutrient culture medium.

Green Patent No. 4,003,789, January 18, 1977, claims a mouse cell line in a suitable growth medium. The claims were rejected as nonstatutory. In repeated responses, the applicant pointed out that the claimed product did not occur in nature but rather was sig-

nificantly modified. Finally, in a brief to the Board of Appeals, the applicant also said:

"... living microorganisms have been held to be patentable subject matter. For example, live viruses in the form of vaccines have been held to be proper subjects for patents as long as they meet the other requirements for patentability. *Ex parte Plotkin*, 174 U.S.P.Q. 39 (P.O. Bd. App., 1971); *In re Bankowski*, 138 U.S.P.Q. 75 (C.C. P.A. 1963); and, *Dick et al. v. Lederle Antitoxin Laboratories*, 6 U.S.P.Q. 40 (S.D.N.Y., 1930)."

The Examiner thereupon withdrew his rejection and the claims were allowed.

In Bordt et al. Patent No. 4,070,453, January 24, 1978, claims to a porcine cell strain were presented. When amended to recite a "suitable culture therefor", they were allowed. (R. App. 11a)

Goldberg Patent No. 4,166,112, August 28, 1979 (R. App. 13a), solicited by the Government from the Government, claims specific bacteria and "a carrier."

These patents clearly claim living things; the additional recitation of such inanimate things as a carrier does not change that fact. Moreover, the Patent Office also has granted patents on living things not claimed with inanimate things.

Treichler et al. Patent No. 3,923,601, December 2, 1975, claims a colony of a fungus mutant, a living thing not combined with anything else.

Smith Patents Nos. 3,356,574, December 5, 1967, and 3,364,117, January 16, 1968, each claims a freeze-dried culture of a different specific bacterium.

Smith et al. Patent No. 3,709,782, January 9, 1973, claims mammal cells, a feline cell line useful in production of vaccines. While the application was never rejected as directed to living subject matter, claims to the cell line were rejected as products of nature. In response, the applicant not only rebutted that rejection but expressly called attention to the living nature of his compositions:

"The fact that some compositions have certain characteristics of living matter is not *per se* an obstacle for their inclusion as statutory subject matter. For example, vaccines, serums, yeast compositions, viral suspensions, and the like, have all been the subject of U.S. patents, and Patent Office classification supports this view. Thus, Class 424/93 covers 'Whole Live Microorganisms or Virus Containing Non-Immunologic Materials . . .'"

After limitation of the cell line claim to recite it as the product of a claimed process, it was then allowed.

The Government's brief (Br. 38-40) criticizes the CCPA for relying on patents cited as covering living matter in an article written by three Patent Office Examiners, 10 IDEA 87 (1966). This article takes the position that patent protection is available for microorganisms and suggests claiming them as compositions of matter. The alleged "consistent" policy of the Patent Office evidently was not communicated to the authors, despite early publication of their views, and their evident responsibility for subject matter of this kind. To the contrary, the article quotes a then Commissioner of Patents as having told the Congress that patents are granted on "cultures," 10 IDEA at 95. The cited Senate Report No. 932, 86th Cong., 1st Sess., 1959, quotes a letter from Commissioner of Patents

Watson dated March 13, 1959, to Senator O'Mahoney, then Chairman of the Senate Subcommittee on Patents. The letter states:

"Patents are granted on cultures and pharmaceuticals; and under the plant patent statute on plants bearing edible fruits and nuts." (page 7)

Cultures are defined in *Fundamentals of Microbiology*, Frobisher et al., Ninth ed., W. B. Saunders Co., Philadelphia, 1974, page 790:

"Any growth, population, or cultivation of microorganisms."

As to several patents referred to by the Patent Examiners in the IDEA paper, the Government states that they "claim a virus, which some scientists consider to be without life." (Br. 39, fn 46).¹² It is assumed, therefore, that Patent Office policy admittedly is that viruses can legitimately be claimed in patents. This conclusion is confirmed by the Board of Appeals decision in *Ex parte Plotkin*, 174 U.S.P.Q. 39 (1971). (Messrs. Magil and Schneider, from the *Chakrabarty* board, were members of the *Plotkin* board.) The searches referred to above have identified nearly 200 patents claiming viruses. It is well that the Patent Office does not seek to invalidate those 200+ patents, as they do the 60+ patents identified herein.

¹² The Government's reference in footnote 47 to Mr. Federico's comment as to Pasteur's yeast patent omits to say that the authority he cited for his doubt concerning patentability was this Court's opinion in *American Fruit Growers v. Brogdex*, 283 U.S. 1 (1931). That decision did not criticize the living nature of the subject, but rather its natural character. Again, *Chakrabarty's* bacterium does not occur in nature.

This is not a case similar to that in *Parker v. Flook*, 437 U.S. 584, 595 (1978) in which the

“... youth of the industry may explain the complete absence of precedent supporting patentability.”

Here, the technology, broadly, is old. The court below quoted the Patent Office Solicitor at oral argument to that very effect (Pet. App. 68a). Moreover, there is an abundance of precedents, supporting patentability, above recited.

Expanding upon a statement made in *Parker v. Flook*, 437 U.S. at 596, the Government appears to contend that only technologies foreseen by Congress at the time it passes a patent law are within that law. Illustrations of technologies certainly not foreseen by Congress when it passed the 1836 Act, the 1874 Act or the 1952 Act are not hard to imagine. Did the 1874 Congress foresee airplanes, photocopying machines, computers, antibiotics? All were patented. Must the Congress re-pass 35 U.S.C. 101 every year to insure that new technologies, the very reason for the statute, are within it? *Application of Sarkar*, 588 F.2d 1330, 1333 (CCPA 1978). This Court has said:

“... if Congress has made a choice of language which fairly brings a given situation within a statute, it is unimportant that the particular application may not have been contemplated by the legislatures.” *Barr v. United States*, 324 U.S. 83, 90 (1945).

Available evidence proves that, before this case, “consistent” Patent Office policy had been to grant patents directed to living things. Here is no extension

of patentable subject matter. Here is reversal of a Patent Office policy and an attempt at restriction of patentable subject matter.

II. CHAKRABARTY'S INVENTION DOES NOT INVOLVE RE-COMBINANT DNA; HAZARDS IN SUCH RESEARCH HAVE PROVEN TO BE LESS THAN EXPECTED; HEW HAS SO RECOGNIZED; CONGRESS HAS REFUSED TO REGULATE; ANY REGULATION SHOULD BE DIRECT

The Government's brief cites controversy connected with research known as “recombinant DNA” as justification for denial of Chakrabarty's claims (Br. 17-21). Those claims do not involve recombinant DNA, as the Government admits (Br. 17-18). Some explanation is necessary to put this point in perspective.

Genes determine the characteristics of microorganisms, as well as those of other types of cells. The principal substance of the genes is deoxyribonucleic acid (DNA).

“DNA plays to two roles: (1) provides information for the reproduction, growth, and functions of the cell, and (2) preserves and directs replication of this information and transfers it to the offspring. These two roles of DNA are common to animals, plants, single-cell organisms, and many viruses. The DNA of cells is mainly found in organized structures called ‘chromosomes’.

“Intracellular DNA also occurs outside of the chromosomes as separately replicating molecules. Such DNA molecules include the plasmids, found in bacteria; ...” Proposed Revised Guidelines, Recombinant DNA Research, National Institutes of Health, DHEW, July 28, 1978, 43 Fed. Reg. 33100.

Materials called "restriction enzymes" are capable of splitting DNA molecules into fragments. Certain ones of these enzymes leave the split fragments with so-called "sticky ends". Recombinant DNA involves associating together genes of different species and then recombining the split fragments by virtue of these "sticky ends". The splitting, associating and recombining all take place outside of the cells, so-called "in vitro", rather than "in vivo". Proposed Revised Guidelines, *supra*, 43 Fed. Reg. 33101. (These guidelines contain an excellent short, simplified description of the recombinant DNA process, with diagram, reproduced at R. App. 20a, 21a.)

Chakrabarty did not use the recombinant DNA method in his research. As the Proposed Guidelines state, recombinant DNA was first successfully practiced in 1973; Chakrabarty's patent application was filed in 1972. Chakrabarty's work was carried out "in vivo", since he caused the plasmids to migrate from cell to cell, without any splitting or recombining outside the cells.

The Government's seizure upon the recombinant DNA matter¹³ demonstrates how far they must go to attempt to justify their policy change toward refusal of patents on living microorganisms. Whether patents are to be granted on the recombinant DNA technique

¹³ The Government's speculation, with the Peoples Business Commission (Br. 18, fn. 19), that patenting leads to reduction in variety, conflicts with the finding of the House Agriculture Committee which recommended passage of the Plant Variety Protection Act, that patenting:

"... will give farmers and gardeners more choice, and varieties which are better in yield or in quality..." 116 Cong. Rec. 40296, December 8, 1970.

or its products is quite a different issue from whether Chakrabarty's different invention is patentable. Nevertheless, a holding here that living bacteria cannot be patented would seriously impact upon recombinant DNA research. The presence here, as *amici*, of organizations involved in such research demonstrates that impact.

While the interests of *amici* are best presented by them, we must here respond briefly to the distortion of the record presented by the recombinant DNA portion of the Government's brief (Br. 18-21).

Concern for the danger of recombinant DNA research has considerably diminished in recent years. The 1976 Guidelines imposed by NIH on recombinant DNA research it sponsors (41 Fed. Reg. 27902, July 7, 1976) were considerably relaxed 2½ years later (Revised Guidelines, etc., 43 Fed. Reg. 60080, December 22, 1978). A recent publication cited in the Government's brief (Br. 20) reports that the committee which generated the Guidelines has recommended a further relaxation, to the point that 80-85% of the area impacted by the original Guidelines would be de-controlled. *Science*, Vol. 205, September 21, 1979, page 1238. On November 30, 1979, NIH published the following statement in the Federal Register:

"Lack of Demonstrated Hazard to Date"

The Environmental Impact Assessment of July 1978 stated, 'No evidence has come to light that any of the thousands of individual recombinant DNA clones constructed over the last 5 years have yielded a product harmful to man or the environment. On the other hand, many examples of useful knowledge obtained through such techniques continue to accumulate rapidly.' The negative aspect of this statement remains unchanged as of

this date. The useful new knowledge obtained through the use of the technology has continued to accrue." 44 Fed. Reg. 69241. (emphasis in original)

Moreover, the Congress, which considered legislating controls on recombinant DNA research, has evidently given up that project. "Science and Technology" the congressionally-mandated report by the National Academy of Sciences, recently had this to say on the subject:

"The anxiety over recombinant DNA research has abated considerably, for several reasons. Among those is the failure of five years experience to produce evidence of any illness or other harm. In addition, sober professional analyses have gradually displaced earlier unrealistic demands for absolute protection against hypothetical risks." Accordingly, the NIH guidelines are gradually being relaxed; and the Congress has determined that the guidelines are adequate for handling the problem without legislation." Science and Technology, A Five-Year Outlook, National Academy of Sciences, W. H. Freeman and Co., San Francisco 1979, page 134.

¹⁴ The "Peoples Business Commission", *amicus curiae*, evidently is a holdout. Having been unsuccessful in other fori, they here seek to discourage affirmance of the CCPA holding which would, they say:

"... significantly contribute to the profit potential of the genetic industry, thus generating a greater momentum in research and development of genetic engineering technologies. This, in turn, will lead to the rapid proliferation of genetic techniques in the areas of energy, agriculture, medicine, industrial processes and many other aspects of the nation's economic life." (page 3).

To a supporter of both private enterprise and the patent incentive for private enterprise, this sounds like an argument for affirmance.

See also letter to Secretary Califano of DHEW, by Senators Kennedy and Javits, respectively, Chairman and Ranking Minority Member of the relevant Senate subcommittee and committee, dated June 1, 1978, reproduced with the Revised Guidelines, Recombinant DNA Research (43 Fed. Reg. 60103-4) December 22, 1978:

"In the past, Congress has been reluctant to extend statutory control over a specific field of scientific investigation unless such authority was absolutely necessary to protect the public's health and safety. In view of the scientific evidence accumulated during the past year, it is not possible to reach this conclusion in the case of recombinant DNA research."

It is axiomatic that any dangers to the public's health and safety are best prevented by regulation of the source of those dangers, not by an indirect approach that would prevent patenting the results of research.¹⁵ Moreover, where the Congress has refused to act to control recombinant DNA research, at the urging of the Government,¹⁶ after "four committees of the House and Senate have held nine series of hearings to consider the issues relating to recombinant DNA research" (Kennedy and Javits letter of June 1,

¹⁵ "The Patent and Trademark Office has nothing to do with regulating use of technology. The Government is adequately supplied with numerous other agencies able and eager to perform that function." *Application of Sarkar*, 588 F.2d 1330, 1333 fn 8 (CCPA 1978) (emphasis in original).

¹⁶ Proposed Revised Guidelines, Recombinant DNA Research, Tuesday, September 27, 1977, 42 Fed. Reg. 49596.

"A Federal Interagency Committee on Recombinant DNA Research recommended in March 1977 that legislation be passed to extend the standards of the NIH Guidelines to all recombinant DNA activities in the public and private sectors."

1978, *supra*),” the Government stands on weak ground in urging discouragement to the research by this Court.

Inconsistency is the very hallmark of the Government’s activities in this area. On January 13, 1977, the Patent Office announced a new program to accord “special status” to patent applications involving recombinant DNA research so as to expedite their consideration, and thereby their publication. The notice emphasized the benefits of such research, saying:

“Recombinant DNA research appears to have extraordinary potential benefit for mankind. It has been suggested, for example, that research in this field might lead to ways of controlling or treating cancer and hereditary defects. The technology also has possible applications in agriculture and industry. It has been likened in importance to the discovery of nuclear fission and fusion.” 42 Fed. Reg. 2712

The special status program was later withdrawn, 42 Fed. Reg. 13147, March 9, 1977,¹⁷ but the same Government which here seeks to discourage recombinant DNA research, encourages that research by hundreds of research contracts sponsored by NIH (500 plus, according to Senator Stevenson’s remarks on the Senate floor on October 14, 1978, Cong. Rec. S 19351. A very recent publication, cited by the Government, quotes a government official that 720 projects are currently sponsored by NIH, *Chemical Week*, September 26, 1979, page 34.)

¹⁷ See also H. Rep. Report No. 95-1005, 95th Cong., 2d Sess., on H.R. 11192.

¹⁸ Patent Office Official Classification Class 435, Subclass 172, is for patents claiming “Mutation or Genetic Engineering.” There are 92 patents in that subclass.

As this brief is being written, the *Washington Post* of January 17, 1980 reports (page A7) researchers’ success in producing interferon by a genetically-engineered bacterium. The prohibitive cost of prior methods of production of that very promising drug is expected to be brought to manageable levels, by use of the new man-made bacterium.

Recombinant DNA research and any controversies concerning it, furnish no basis for denying patents on bacteria because they are alive. Indeed, inhibition to the making and disclosure¹⁹ of recombinant DNA inventions, by outlawing patents on living microorganisms, may adversely affect that research and its great promise for mankind.

III. THE GOVERNMENT’S MISCELLANEOUS “AUTHORITIES” DO NOT SUPPORT ITS CONTENTION THAT MICRO-ORGANISMS HAVE ALWAYS BEEN UNPATENTABLE

While ignoring the objective evidence furnished by the patents it has issued, both those in litigation and the great majority which were not, and its own official patent subclass classification, the Government relies on admitted dicta, obviously equivocal, the title of a resolution adopted by a bar association and various other “authorities”. Their weight, even if added together, does not approach that of the objective evidence to the contrary.

¹⁹ A graphic example of the significance of the patent to disclosure of an invention is furnished by the recent case of *Application of Sarkar*, 588 F.2d 1330, 1332, 1333 (CCPA 1978). The applicant was desirous of preserving his trade secret rights in his mathematical formula and therefore successfully requested *in camera* treatment of the formula. Since the court affirmed the Patent Office rejection, the patent will not be granted and the formula will not be published.

Guaranty Trust Co. of New York v. Union Solvents Corp., 54 F.2d 400 (D. Del. 1931) *aff'd* on the lower court opinion 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933), concerned a patent on a method of producing acetone and butyl alcohol by use of a bacterium which Mr. Weizmann had found in nature. The patent was sustained, the court rejecting the contention that it was for the life process of a living organism. The court contrasted the bacterium, found in nature and therefore not novel, with the method of its use:

"Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the life process of a living organism. Were the patent for bacteria *per se*, a different situation would be presented. As before stated, the patent is not for bacteria *per se*. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set forth in the specification and claims. Undoubtedly there is patentable subject matter in the invention." 54 F.2d at 410.

Since the bacterium was old in nature, it might well have been unpatentable if claimed alone, which it was not. In any event, comments on patentability of non-existent claims clearly were dicta.

Similarly, in *Application of Mancy*, 499 F.2d 1289 (CCPA 1974), the court, per Judge Rich, was concerned with claims to a process of producing a specific antibiotic, by use of a particular microorganism which had been found in nature. The court was not concerned with claims to the microorganism itself, but rather only with claims to the method. Nevertheless, it made the following expressly qualified statement:

"Here appellants not only have no allowed claims to the novel strain of *Streptomyces* used in their

process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature'." 499 F.2d at 1294.

In his opinion below, the same Judge Rich emphasized that the purpose of the quoted statement was merely a comparison between the facts of *Mancy* and those of *Application of Kuehl*, 475 F.2d 658 (CCPA 1973), in which the involved catalyst was itself claimed, as was the method of its use. No comment on patentability of living organisms was intended. Only a comment, later questioned, on novelty of the microorganism. (Pet. App. 46a-47a.)

The Government's criticism of the interpretation below of the language in *Mancy* (Br. 13, fn. 11) sounds like a return to the Examiner's "product of nature" rejection, rejected by the Board of Appeals (Pet. App. 163a). In any event, the comparison is admittedly relevant only to *Bergy*, not to this case.

The Government also contends (Br. 14, fn. 11) that "the issue of living organism patentability was raised, but not decided in *Application of Merat*, 519 F.2d 1390, 1363 (CCPA 1975)." That is not correct. The Board had said that "a thing occurring in nature" may not be patented. The CCPA did not decide that issue but sustained the rejection on other grounds.

We must again emphasize that the "product of nature" rejection, recognized by the official Manual of Patent Examining Procedure § 706.03(a) (R. App. 1a), applied by the Board in *Merat* and referred to by the court in *Mancy* is not the same as the "living thing" rejection. The Board of Appeals below recog-

nized the difference, overruling the "product of nature" rejection as to Chakrabarty (Pet. App. 163a), though applying the new unrecognized "living thing" rejection in conflict with its earlier decisions.

The American Bar Association Section of Patent, Trademark and Copyright Law did not act on the title relied on by the Government's extended footnote (Br. 14, fn. 12). It acted only on the resolution. That resolution favors "application of the principles of the Patent System to all the agricultural arts (including all plants, sexual seed breeding, micro-organisms, and animal husbandry)". 1966 *Summary of Proceedings* 74, Section of Patent, Trademark and Copyright Law, American Bar Association. Of course the Chakrabarty bacterium is not within the agricultural arts. The resolution does not apply. Moreover, that resolution and the American Patent Law Association resolution excerpted in the same footnote, respectively, were anticipation of, and reaction to, a proposal in the 1966 Report of the President's Commission on the Patent System. That Report recommended sweeping changes to the patent laws, including elimination of patent protection for plant patents. Both patent law organizations opposed that recommendation.

The ABA committee report recommending the Government-cited resolution stated the following:

"There is no logical reason why asexually reproduced plants and microorganisms should be covered by patents as at present, while sexually reproduced ones are not covered by patents." 1966 *Committee Reports* 77, Section of Patent, Trademark and Copyright Law, American Bar Association.

Chakrabarty's bacterium is asexually reproduced. Does the Government agree with the committee whose

work it quotes, that the patent law in 1966 covered asexually reproduced microorganisms? If so, they contradict their own principal contention here.

It is noteworthy that the patent law revision bills (containing an entire proposed Title 35) recommended by the same ABA committee during the next year contain no provision for "extending" patent protection to microorganisms. 1967 *Summary of Proceedings*, Special Meeting, Washington, D. C., pages 33-62, 106-139; *Same*, Honolulu, pages 68-78, 81-101, 152-179. Perhaps the committee recognized it to be unnecessary to do so, because microorganisms are within existing law.

In any event, the same ABA Patent Section supported the holding below that existing law does not foreclose patenting living bacteria, at 1978 *Summary of Proceedings* 31 (noted below at Pet. App. 6a).

The Government's references to 1969 and 1976 ABA Patent Section actions, concern amendment of the Plant Patent law to include microorganisms, an entirely different matter than whether 35 U.S.C. 101 covers microorganisms. In the first place, there was an express authoritative holding that microorganisms were not plants, within the meaning of the then-existing plant patent laws. *In re Arzberger*, 112 F.2d 834 (CCPA 1940). In the second place, if the statute was amended to overrule *Arzberger* and qualify microorganisms as plants, the relaxation of the disclosure requirements of 35 U.S.C. 112, provided to plants by Section 162, would also be applicable to microorganisms. It is not now applicable. That the Patent Section may have desired that result is not at all relevant to

whether bacteria are patentable under Section 101, because they are alive.

The bar association activities are not support for the Government's position.

Cited text writers did not state that microorganisms are outside the present law. Mr. Dienner of course was concerned with plants and animals, not with microorganisms. Neither he nor the other writers cited by the Government (Br. 14, 15) suggested that the living nature of the things they wished patented, prevented their being patented.

The capabilities of the Congress in passing legislation for the future (Br. 16, 17) are not relevant to the coverage of existing law.

The difficulty of description of microorganisms (Br. 16, fn. 14) has been solved by the Government-approved deposit procedure. The CCPA has approved this procedure in *Application of Argoudelis*, 434 F.2d 1390 (1970) and *Feldman v. Aunstrup*, 517 F.2d 1351 (1975), *cert. denied* 424 U.S. 912 (1976). The Government's reference to that already-solved problem is no more support for denial of claims to the deposited bacterium than it would be to the combination of the bacterium with a carrier, or to the method of use of the bacterium. (As pointed out above, claims to these subjects have been allowed.)

But the Government's criticism of the CCPA for not explaining why its conclusion does not apply to subject matter not before the court (Br. 17, fn. 16) is the most incredible assertion of all. The hypotheticals suggested as to other living organisms are properly decided when cases or controversies involving

those subjects matter are presented. In any event, the solution to the description problem furnished by the aforesaid deposit system obviously would not apply to animals and humans. Clearly, problems in providing an enabling disclosure would be present and likely would bar patenting. As to humans, constitutional problems would seem to afflict a patent granting someone the right to exclude others from reproducing a human being. A more precise consideration is appropriately postponed until a case or controversy makes a decision necessary.

The Government's authorities do not prove its thesis.

IV. CHAKRABARTY'S BACTERIUM IS WITHIN THE STATUTORY CLASSES OF SECTION 101

Chakrabarty's man-made bacterium, a composition of a bacterium having at least two plasmids each establishing a degradative pathway for a different oil component, is within either or both of two classes of subject matter established by Congress.²⁰ Section 101 of Title 35, U.S.C. Code states:²¹

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement

²⁰ Clearly, the bacterium relates to the "useful arts", the constitutional objective of the patent system. Constitution, Article I, Section 8, Clause 8

"The Congress shall have Power . . . [8] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. . . ."

Any more "useful art" than cleanup of oil spills would be hard to imagine. The Government does not suggest otherwise.

²¹ 66 Stat. 792.

thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

A. Manufacture

The term "manufacture" has an extremely broad connotation. In the Committee Report on the legislation which became Title 35, the following was said as to that term in Section 101:

"A person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, . . ."²²

That language goes back to the oft-cited language of *Johnson v. Johnston*, 60 Fed. 618, 620 (W.D. Pa. 1894):

"The term 'manufacture', as used in the patent law, has a very comprehensive sense, embracing whatever is made by the art or industry of man, not being a machine, a composition of matter, or a design. Curt. Pat. § 27, 1 Rob. Pat. § 183."

The following courts of appeals cases quoted *Johnson* with approval: *Binney & Smith Co. v. United Carbon Co.*, 125 F.2d 255 (4th Cir. 1942), reversed on other grounds, 317 U.S. 228 (1942); *Riter-Conley Mfg. Co. v. Aiken*, 203 Fed. 699, 701 (3d Cir. 1913), cert. denied 229 U.S. 617 (1913); *International Mausoleum Co. v. Sievert*, 213 Fed. 225 (6th Cir. 1914). To the same effect are *Park-In Theatres v. Rogers*, 130 F.2d 745, 747 (9th Cir. 1942) and *In re Hadden*, 20 F.2d 275 (D.C. Cir. 1927).

²² H.R. Rep. No. 1923, 82d Cong., 2d Sess. (1952), page 6; Senate Rep. No. 1979 (1952), U.S. Code, Cong. and Admin. News, page 2399.

Decisions of this Court are not contrary. In *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931) citrus fruit whose skin carried a small amount of borax was held not to be a "manufacture", the Court expressly stating:

" 'Manufacture,' as well defined by the Century Dictionary, is 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.' Also, 'anything made for use from raw or prepared materials.'"

"Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore." 283 U.S. at 11, 12.

A patent to a treated fur was challenged upon the authority of *American Fruit Growers*, in *Steinfur Patents Corp. v. Beyer*, 62 F.2d 238, 240 (2d Cir. 1932). Rejecting the challenge, the court said:

"It can hardly be doubted that a naturally dark-colored skin which has been bleached and dyed a light color is an article of manufacture. Certainly it cannot be said of it, as of the orange, that there is no change in its 'name, appearance or general character.' In none of the three stages sought to be protected by the present patent were the dressed skins in their natural state. While it was true of the orange that impregnation of its rind with borax only protected the natural article against

deterioration by mold and gave it no new beneficial uses, the same cannot be said of impregnation of the unbleached skin with ferrous sulphate. By such impregnation the skin attains a new quality which gives it a new beneficial use; it fits it to be used for bleaching by a method which could not without such impregnation be successfully employed. An orange has the same use whether or not impregnated with borax. A fur skin unimpregnated with ferrous sulphate cannot be used in the same way as one which has been so impregnated. The orange case does not, in our opinion, require a decision that the product patent in suit is invalid."

Chakrabarty's bacterium not only has a changed name, it has a new and distinctive form, quality and property. That is, the new bacterium has a plurality of plasmids coded for different oil components, and these plasmids enable the single bacterium strain to digest plural component oil. Under the *Brogdex* test, like the patented fur, Chakrabarty's bacterium is a "manufacture".

B. Composition Of Matter

Deller's *Walker on Patents*, 2d edition, Baker, Voorhis & Co., Inc., 1964, a standard treatise, says this about "composition of matter":

"The phrase 'composition of matter,' as used in the patent statutes, covers all compositions of two or more substances. It includes all composite products whether they are the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." § 18, pages 127, 128.

A much older text "The Law of Patents for Useful Inventions" by William C. Robinson, Little, Brown and Company, 1890, says:

"A composition of matter is an instrument formed by the intermixture of two or more ingredients, and possessing properties which belong to none of these ingredients in their separate state." § 192, page 278.

In *P. E. Sharpless Co. v. Crawford Farms, Inc.*, 287 Fed. 655, 658 (2d Cir. 1923) appears the following:

"A patentable composition of matter may well result or be formed by the intermixture of two or more ingredients, which develop a different or additional property or properties which the several ingredients individually do not possess in common."

Chakrabarty's bacterium contains two or more plasmids providing it with the new capability of itself degrading two or more components of oil. Thereby, the bacterium has properties which belong to none of its individual ingredients, its separate plasmids.

The CCPA held that Chakrabarty's bacterium was either a "manufacture" or "composition of matter", finding it unnecessary to distinguish between them (Pet. App. 44a). In doing so, the court called attention to the fact that the Patent Office had allowed claims to the bacterium on a carrier:

"... the PTO [Patent & Trademark Office] obviously has no hesitation in issuing a patent on the living bacterium or inoculum when applied to or mixed with straw, which combination it must consider to be a manufacture or a composition of matter under § 101. . . ." (Pet. App. 35a.)

The Patent Office Board of Appeals admitted that the language of the statute does not exclude living organisms (Pet. App. 161a). Here, the Government does not contend otherwise. Chakrabarty's bacterium properly was held to be within the statutory classes.

V. CONGRESSIONAL INTENT CONCERNING LIVING MICRO-ORGANISMS WAS NOT EVIDENCED BY PASSAGE OF THE PLANT PATENT ACT (1930) OR THE PLANT VARIETY PROTECTION ACT (1970)

The Government here contends that the passage of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 by much later Congresses is evidence that patents to all living things were excluded from the terminology "manufacture" and "composition of matter" chosen by much earlier Congresses.

The most that can be said is that the Congress believed in 1930 that plants were not patentable under the prior patent law. The legislative history of the Plant Patent Act, however, does not reveal either by expression or by implication, that the living nature of plants was what placed them outside the scope of the patent law.

A brief review of the background of the Plant Patent Act is in order.

The Commissioner of Patents in 1889 held in *Ex parte Latimer*, 1889 C.D. 123, 46 O.G. 1633 that claims to a component of a pine tree were not patentable. Latimer claimed "a new article of manufacture" consisting of parts extracted from needles of particular species of pine tree. The process of extraction was

patented but claims to the product were refused. The Commissioner stated:

"... the mere ascertaining of the character or quality of trees that grow in the forest and the construction of the woody fiber and tissue of which they are composed is not a patentable invention, recognized by the statute, any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found . . ." 1889 C.D. at 125.

The Commissioner also said:

"that . . . patents might be obtained upon the trees of the forest and the plants of the earth . . . of course would be unreasonable and impossible." 1889 C.D. at 126.

Latimer did not convert the material of the pine needle to a patentable manufacture merely by extracting it. However, if he had taken additional steps to cause the extract to have a new quality or function, the modified extract would have been a manufacture, and thus within the statutory classes of invention.

"If applicant's process had another final step by which the fiber thus withdrawn or separated from the leaf or needle in its natural state were changed, either by curling it or giving it some new quality or function which it does not possess in its natural condition as fiber, the invention would probably cover a product, because the natural fiber, passing through the exigencies of such a process would be treated and become something new or different from what it is in its natural state." 1889 C.D. at 127.

There is marked similarity between this reasoning and the comments of this Court in holding invalid the

borax-coated orange patent in *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931).

Under the rationale of *Latimer*, it appears that the work of the plant breeder did not qualify for a patent because there was insufficient change in the plant caused by man. As said in one of the Government's authorities, a biography of Luther Burbank:

"When two plants are united to produce a third, no human intelligence can predict just what will follow." *New Creations in Plant Life*, W. S. Harwood, The MacMillan Co., 1905, page 31.

The "general character" of Burbank's work was said to be in two forms:

"1. Breeding.—This, in its basic meaning, consists in uniting two plants to give birth to a third.

* * *

Breeding is accomplished by sifting the pollen of one plant upon the stigma of another, this act, pollination, resulting in fertilization, Nature, in her own mysterious ways, bringing forth the new plant.

2. Selection.—This consists in eternally choosing the best and rejecting the worst. It is co-equal in importance with breeding, the one supplementary to the other at all points." *Id.*, page 25.

Though labor, mental and physical, was certainly involved, both in breeding and selection, it apparently was concluded that insufficient change to the plant was caused by man (rather than nature) to make the new plant a manufacture. It remained a product of nature.

The Government seeks to compare Chakrabarty's work with that of the ordinary plant breeder (Br. 27,

fn. 32; Br. 33-34, fn. 39-40). The great difference is apparent from Chakrabarty's own description of his work (App. 46-47). He repeatedly transferred plasmids from cell to cell and purified the results, all to obtain exactly what he set out to obtain, a strikingly new plural plasmid bacterium capable of digesting multiple oil components. As the Patent Office Board of Appeals expressly found (Pet. App. 163a) that product was made by Chakrabarty, *not* by nature. To be sure, some plant breeders did more than merely allow nature to modify; some used drugs, others used radiation. Whether the results of such work were or were not patentable is not known. But the 1930 Act was not directed at such work. The ordinary plant breeder's efforts qualified, if the result was a new and distinct variety.

In any event, it became an accepted tenet of patent law that plants were not patentable. The work of plant breeders such as Luther Burbank was, of course, extremely valuable, but lack of patent protection made it impossible to prevent copying.

To provide incentive for breeders, the Congress was petitioned to amend the patent law to allow patents on plants. By 1923 the clamour was sufficiently loud that an article on the subject was published in the primary journal of patent law, the *Journal of the Patent Office Society* (Thorne, "Relation of Patent Law to Natural Products," 6 JPOS 23 (1923)). That article expressed the view that the product of the plant breeder was outside the existing patent law because it was a natural product. Reliance was placed on *Ex parte Latimer, supra.*, and on the law of nature cases, *Morton v. N.Y. Eye Infirmary*, Fed. Case No. 9865,

17 Fed. Cas. 879 (C.C. S.D. N.Y. 1862) and *Wall v. Leck*, 66 Fed. 552 (9th Cir. 1895).²³

The legislative history of the 1930 Plant Patent Act (Act of May 23, 1930, 46 Stat. 376) is consistent with the product of nature explanation. Commissioner of Patents Robertson referred to an earlier law of nature decision, *In re Kemper*, Case No. 7,687, 14 Fed. Cases 286 (C.C. D.C. 1841), in responding to a less limited version of the legislation than actually passed the Congress. Under that version (H.R. 9765, S.3530, 71st Cong., 2d Sess.) a mere plant finder would have been entitled to a patent for exclusive asexual reproduction of the found plant. Robertson said:

"... a very serious question arises as to whether the definition given the words 'invention' and 'discovery' in the proviso in the bill, namely, that they shall be interpreted 'in the sense of finding a thing already existing and reproducing the same as well as in the sense of creating,' does not go beyond the power which the Constitution grants to Congress. Under that proviso the person who is given the right to get a patent, if the found variety is new, has done nothing whatever in any way toward creating that variety." Hearings Before the Committee on Patents, House of Representatives, 71st

²³ The Ninth Circuit in *Wall* pointed out the difference between a natural product and a manufacture:

"The laws . . . do not permit any man to exclusively use the conditions which are the gifts of nature, simply because he was the first one to discover its value. Not until some new instrument or method is contrived for its direction towards ends which it cannot naturally accomplish does his creative genius manifest itself." 66 Fed. at 558.

Here, Chakrabarty's bacterium simultaneously degrades multiple components of oil, an end not accomplished by a mixture of naturally occurring bacteria.

Cong., 2d Sess., on H. R. 11372, April 9, 1930, page 6.

Underlining his concept that a plant was not made by man, as was a manufacture under existing law, Commissioner Robertson suggested revision of the statute defining the patentees' right to exclude, saying:

"This suggestion is made because the word 'make' in the statute is usually understood to mean the construction by human activity whereas these plants are reproduced by growth, a person only putting the graft or scion, for example, in such a position, in the tree to be grafted upon, that it will grow." *Id.*, at 7.

The Commissioner also called attention to the difficulty of a plant inventor complying with the enabling disclosure requirements of the patent law, by which an inventor's description must be sufficient to enable a reader to reproduce the invention. He suggested relaxation of the disclosure requirements as to plants.

As a direct result of the Commissioner's comments: 1) the proviso which would have permitted a patent to a plant finder was eliminated; 2) R.S. 4884 was revised to qualify asexual reproduction as an act of infringement; and 3) the suggested relaxation of the disclosure requirement was adopted. H.R. 11372 and S. 4015 were introduced to implement these suggestions. (S. 4015 contained the finder provision, as introduced. However, as reported, that provision was omitted.)

Pointedly, the Commissioner made no reference whatever to the living nature of plants, or any other living thing, as preventing patenting. Nor did the Committee Reports.

By skillful quotation out of context, the Government seeks to create a different impression. The inanimate nature of the mineral (Br. 32) was not the Committee's emphasis, but rather the natural character of the mineral. Product of nature vs. product of man was the emphasis.²⁴ Also emphasized was the manual act of asexual reproduction, which was required by the bill before a patent could be granted. The Committee's statement was a rebuttal to the suggestion that the work of a plant breeder was mere discovery of a product of nature:

"There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man and is likely to be discovered in various parts of the country; and, being the property of all those on whose land it may be found, its free use by the respective owners should of course be permitted. On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man, and such discoveries can only be made avail-

²⁴ Commissioner of Patents Watson, in 1954, confirmed that interpretation in commenting on a bill (now law) which would make newly found seedlings patentable under the plant law:

"... the primary basis for holding the law then under consideration [Plant Patent Act] to be constitutional was that there is a 'clear and logical distinction' between the finding of a mineral which 'is created wholly by nature unassisted by man' and a 'plant discovery resulting from cultivation' which cannot 'be reproduced by nature unaided by man.'

"It has been consistently held in other fields that the mere discovery of an article or composition which is old in nature cannot in itself form the basis for a patent." S. Rep. No. 1937, July 19, 1954, 83rd Cong., 2d Sess., 1954 U.S. Code Cong. & Admin. News 3981, 3983-4.

able to the public by encouraging those who own the single specimen to reproduce it asexually and thus create an adequate supply.

"It is obvious that nature originally creates plants but it can not be denied that man often controls and directs the natural processes and produces a desired result. In such cases the part played by nature and man can not be completely separated or weighed or credited to one or the other. Nature in such instances, unaided by man does not reproduce the new variety true to type." H.R. Rep. No. 1129, 71st Cong., 2d Sess., page 7; S. Rep. No. 315, 71st Cong., 2d Sess., page 6.

Moreover, the two references in the Committee Reports to the letter from the Secretary of Agriculture (Br. 24-25) were not to the Secretary's opinion that the patent laws then covered only "inventions or discoveries in the field of inanimate nature." As apparent from the material just quoted, the Committees were aware that inanimate natural things were not patentable, even if Secretary Hyde was not. Clearly, they relied on no such opinion. What they did rely on was his approval of the proposed legislation (H.R. Rep. No. 1129, *supra*, at page 3) and his comments on use of Agriculture Department materials and personnel in determining novelty of plant varieties (H.R. Rep. No. 1129, *supra*, at page 6). For patent law, the Committees relied on the Commissioner of Patents.

The 1930 Plant Patent Act was passed within three months of introduction of the initial bills. A single 40 minute hearing was held in the House; none in the Senate. Both chambers of the legislature were obviously receptive to the need to create patent protection for plants.

The history with respect to patents directed to single cell organisms, such as fungi, yeast and bacteria, is quite different from the history regarding plants. In direct contrast to the accepted tenet that plants were not patentable, the Patent Office was issuing patents with product claims that included single cell organisms.

The following patents were identified in the search described earlier:

<i>Date</i>	<i>Inventor</i>	<i>Patent No.</i>	<i>Claims</i>
1873	Pasteur	141,072	Purified Yeast
1908	Coates	899,155	Ground vegetable or animal matter inoculated with bacteria
1910	Collett	952,418	Bacteria mixed with cocoa
1914	Earp-Thomas	1,099,121	Sterilized soil inoculated with bacteria
1914	Odle	1,120,330	Food product containing lactic acid bacilli
1916	Palma	1,178,941	Bacteria combined with nitrates
1918	Harris et al.	1,260,899	Lactic acid bacteria and inert material
1923	Stoltz	1,442,239	Nitrifying bacteria combined with calcium carbonate, phosphate rock, and humus
1923	Whitmore	1,457,097	Microorganism in vegetable oil
1925	Reichel et al.	1,540,951	Lactobacillus and culture media
1930	Earp-Thomas	1,758,937	Lactobacteria and culture medium in emulsion

In each of the above patents, a claim was granted either to a live organism alone or to a live organism as one element of a composition; a live organism was a critical element in each claim. These patents demonstrate that the Patent Office did not regard the fact that an organism was alive as a disability to directing claims to it.

In 1930, plants were understood not to be patentable subject matter. The 1930 Plant Patent Act was a step taken by Congress to extend the ambit of patents into an area in which patents had previously been considered not to extend. As the opinion below properly notes, the focus of Congress was solely on plants. The Government has not demonstrated that any comparable disability applied to single cell organisms such as fungi, yeast and bacteria, and the above patents demonstrate that none existed. No comparable legislation was needed or considered in the case of fungi, yeast or bacteria.

The Government here has seized upon an action by the 1930 Congress which expanded patent protection and is attempting to use it as a basis to restrict patent protection in another area. The action of the 1930 Congress was an endorsement of the vitality of patents; it is wholly antithetical to the underlying positive concept of the 1930 Plant Patent Act to use it now, by contrived inference, in a negative fashion as a basis to exclude subject matter which previously has qualified for patent protection.

The Government's hypothesis that the 1930 Plant Act clearly established that living organisms were not patentable is further negated by the fact of continued issuance of patents to such organisms.

For example:

Date	Inventor	Patent No.	Claims
1932	Farr	1,851,165	Milk curd containing living <i>Bacillus acidophilus</i>
1932	Sinden	1,869,517	Cereal substrate inoculated with mushroom mycelium
1933	Torok et al.	1,894,135	Yeast combined with bacterium
1934	Reichel et al.	1,957,555	Stabilized lactobacilli concentrate
1935	Mazzucchi	1,989,014	Anthrax spore in medium containing saponin.
1936	Fowler	2,027,374	Live <i>Bacillus alcaligeres</i> in a mouth wash
1937	Loughlin	2,096,377	Inoculum containing bacterial culture
1937	Hendrickson	2,098,918	<i>Rhizobium</i> bacteria on silica gel
1938	Nordsiek	2,121,442	Mixture of bacteria
1939	Winegarden	2,151,364	Anthrax spore in medium containing aluminum hydroxide
1940	Bond	2,200,532	Mixture of bacteria
1941	Lescarboursa	2,262,851	Root pulp with mushroom mycelium
1942	Meier	2,268,955	Bacteria strain and bacterial products from cultivation on plasma

It is against this background of granting patents directed to living organisms that the 1952 Patent Act

retained the terms "manufacture" and "composition of matter." Congress could have amended the Act then, or later, to specifically exclude microorganisms or living things but it did not choose to do so.²⁵

The Government also attempts to use as evidence for its thesis the Plant Varieties Protection Act of 1970. That Act is even less relevant than the 1930 Plant Patent Act. The Government agrees (Br. 27) with the interpretation by the court below that the exclusion of fungi and bacteria from this Act was merely legislative recognition of the CCPA's earlier decision in *In re Arzberger*, 112 F.2d 834, 837 (CCPA 1940) that bacteria were not plants under the 1930 Act. Moreover, the Committee Report clearly establishes that the enactment of the 1970 Act did not change the patent laws:

"The Committee accordingly has examined S. 3070 and finds that it does not alter protection currently available within the patent system." S. Rep. No. 91-1246, 91st Cong., 2d Sess., page 3.

As the CCPA pointed out (Pet. App. 51a), this Court frequently has held:

" '[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one.' *United States v. Price*, 361 U.S. 304,

²⁵ Specific exclusions, of course, can and have been made by the Congress, where that body deemed that patents should not be available. For instance, the Atomic Energy Act of 1946 excluded patent protection for inventions:

" . . . useful solely in the production of fissionable material or in the utilization of fissionable material or atomic energy for a military weapon." Section 11a1, 60 Stat. 755

That exclusion was repeated in a more limited way in the Atomic Energy Act of 1954, 68 Stat. 919, 42 U.S.C. 2181.

313 (1960); *accord, United States v. Southwestern Cable Co.*, 392 U.S. 157, 170 (1968); *United States v. Philadelphia National Bank*, 374 U.S. 321, 348-49 (1963); *Rainwater v. United States*, 356 U.S. 590 (1958); *United States v. United Mine Workers*, 330 U.S. 258, 281-82 (1974)."

This is particularly true when the later Congress doesn't even express its view of what the earlier Congress intended. The 1930 Congress nowhere stated a view of the intent of earlier Congresses as to living subject matter and the 1970 Congress did not purport to change the scope of patent protection. Since the Patent Office, which has the obligation of administering the patent laws, granted patents on living things both before and after the 1930 Act, patent protection for bacteria is and has been permitted by the patent statutes.

Chakrabarty's man-made bacterium, being a manufacture or a composition of matter, is within the scope of 35 U.S.C. 101. Its living character does not foreclose patentability as consistent interpretation by the Patent Office, prior to this case, shows. If the Government wishes to reverse its policy, it should address its desires to the Congress, which can legislate an exclusion, if that is found to be required by the public interest. In the meantime there is no justification for this Court to read the limitation to nonliving subject matter into the patent law. As the court below stated (Pet. App. 70a), this Court said in *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933):

"We should not read into the patent laws limitations and conditions which the legislature has not expressed."

CONCLUSION

For the foregoing reasons, the judgment of the United States Court of Customs and Patent Appeals should be affirmed.

Respectfully submitted,

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APPENDIX

MANUAL OF PATENT EXAMINING PROCEDURE

706.03(a) Nonstatutory Subject Matter

Patents are not granted for all new and useful inventions and discoveries. The subject matter of the invention or discovery must come within the boundaries set forth by 35 U.S.C. 101, which permits patents to be granted only for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."

The term "process" as defined in 35 U.S.C. 100, means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

Decisions have determined the limits of the statutory classes. Examples of subject matter not patentable under the Statute follow:

PRINTED MATTER

For example, a mere arrangement of printed matter, though seemingly a "manufacture," is rejected as *not being within the statutory classes*. See *In re Miller*, 164 USPQ 46, 57 CCPA 809 (1969); *Ex parte Gwinn*, 112 USPQ 439 (Bd. App. 1955); and *In re Jones*, 153 USPQ 77, 54 CCPA 1218 (1967).

NATURALLY OCCURRING ARTICLE

Similarly, a thing occurring in nature, which is substantially unaltered, is not a "manufacture." A shrimp with the head and digestive tract removed is an example. *Ex parte Grayson*, 51 USPQ 413.

METHOD OF DOING BUSINESS

Though seemingly within the category of a process or method, a method of doing business can be rejected as not being within the statutory classes. See *Hotel Security Checking Co. v. Lorraine Co.*, 160 Fed. 467 and *In re Wait*, 24 USPQ 88, 22 CCPA 822 (1934).

SCIENTIFIC PRINCIPLE

A scientific principle, divorced from any tangible structure, can be rejected as not within the statutory classes. *O'Reilly v. Morse*, 15 Howard 62.

This subject matter is further limited by the Atomic Energy Act explained in § 706.03(b).

UNITED STATES PATENT OFFICE

3,420,742

Patented Jan. 7, 1969

MILK FERMENTING PRODUCT AND METHOD
OF MAKING SAME

STEWART M. FARR, Kalamazoo, Mich., assignor to Dairy
Technics, Inc., Kalamazoo, Mich., a corporation of
Michigan

No Drawing. Continuation-in-part of application Ser. No.
285,858, June 6, 1963. This application Oct. 16, 1964,
Ser. No. 404,526

U.S. Cl. 195-59
Int. Cl. C12k 3/00

16 Claims

ABSTRACT OF THE DISCLOSURE

A method of producing a mixed bacterial concentrate which comprises separately incubating in separate culture media two or three types of bacteria, the first type being selected from the group consisting of *Streptococcus lactis*, *Streptococcus cremoris*, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, and the third type consisting of *Streptococcus diacetylactis*, concentrating the respective media to obtain separate concentrates of the two or three type of bacteria, mixing together the two or three types of bacteria in the desired proportions to produce a mixed concentrate without permitting further growth of the bacteria, and then freezing the mixed concentrate so that it can be stored for a long time without major loss in the viability of the bacteria. A stabilized mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of two or three types of bacteria, as afore-

said, the concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium and the concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

What Is Claimed Is:

4. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of two types of bacteria, the first type being selected from the group consisting of *Streptococcus lactis*, *Streptococcus cremoris*, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, and the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

5. A stabilized mixed bacteria concentrate according to claim 4, in which the concentrate contains at least about 10×10^9 cells per ml.

6. A stabilized mixed bacteria concentrate according to claim 4, in which the stabilizing agent is glycerol.

7. A stabilized mixed bacteria concentrate according to claim 4, in which the bacteria of said first type comprise of at least about 88% of the total count in the bacteria concentrate.

10. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of three types of bacteria, the first type being selected from the group consisting of *Streptococcus lactis*, *Streptococcus*

cremoris, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus* and the third type consisting of *Streptococcus diacetylactis*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

11. A stabilized mixed bacteria concentrate according to claim 10, in which the concentrate contains at least about 10×10^9 cells per ml.

12. A stabilized mixed bacteria concentrate according to claim 10, in which the stabilizing agent is glycerol.

13. A stabilized mixed bacteria concentrate according to claim 10, in which the bacteria of the second type comprise about 8% of the total count of the bacteria concentrate, the bacteria of the third type comprise between about 1% and 4% of the total count of the bacteria concentrate, the balance being bacteria of the first type.

14. A stabilized bacteria concentrate consisting essentially of a substantially neutralized concentrate of a bacteria selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, the concentrate being frozen so it can be stored for a long time without major loss in the viability of the bacteria, the concentrate containing at least about 10×10^9 cells per ml.

15. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of two types of bacteria, the first type consisting of *Streptococcus lactis*, and the second type being selected from the group

consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

16. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of three types of bacteria, the first type consisting of *Streptococcus lactis*, the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, and the third type consisting of *Streptococcus diacetylactis*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

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Group 170
Appeal No. 822-58

Paper No. 19
RHI

IN THE UNITED STATES PATENT OFFICE

BEFORE THE BOARD OF APPEALS

Ex parte Stewart M. Farr

Application for Patent filed October 16, 1964, Serial No. 404,526. A Milk Fermenting Product and Method of Making Same.

Woodhams, Blanchard and Flynn for appellant.

Before Asp, Magil and Behrens, Examiners-in-Chief.
Asp, Examiner-in-Chief.

This is an appeal from the final rejection of claims 5 through 8, 11 through 14, 17, 18 and 19. Claims 1, 2, 3, 9 and 10 stand allowed.

Claim 5 is reproduced as illustrative.

5. A stabilized, mixed bacteria concentrate consisting essentially of a substantially neutralized mixture of two types of bacteria, the first type being selected from the group consisting of *Streptococcus lactis*, *Streptococcus cremoris*, *Lactobacillus bulgaricus* and *Streptococcus Thermophilus*, and the second type being selected from the group consisting of *Streptococcus citrovorus* and *Streptococcus paracitrovorus*, said concentrate being stabilized by the admixture of a stabilizing agent and a nutrient medium so that the concentrate is stabilized against rapid loss of viability, said concentrate being frozen so that it can be stored for a long period of time without major loss in the viability of the bacteria.

No references have been relied upon.

Claims 5 through 8, 11 through 14, 17, 18 and 19 have been rejected as not defining an invention within the meaning of 35 U.S.C. 101. This is the sole issue in the case since

the rejection on the prior art was withdrawn. The Examiner appears to have interpreted these claims as being for mixtures of bacteria which are nothing more than the unpatentable discovery of a handiwork of nature on the authority of *Funk Brothers Seed Company v. Kalo Inoculant Company*, 333 U.S. 127; 1948 CD 671; 608 OG 641; 76 USPQ 280.

Appellant denies the applicability of this decision to the instant claims which define a composition in the frozen state containing bacteria in admixture with additional ingredients, namely, a nutrient medium and a stabilizing agent (glycerol). His invention, he says, is not "a discovery of nature" but rather the "nonobvious manipulation, utilization or application of known things to produce a utilitarian tangible composition of matter." We believe this to be the correct view of the nature of the invention. The holding of the majority in the case relied upon by the Examiner seems to have been based upon a lack of invention in the claimed mixture of strains of *Rhizobium* bacteria following which the decision concluded with the statement that "... we do not consider whether the other statutory requirements contained in 35 U.S.C. § 31, R.S. § 4886 are satisfied." In any case the claims before us are readily distinguishable from the subject matter considered in the *Funk v. Kalo* decision.

We note that the patents cited in the Examiner's action, Paper No. 4, contain claims to cultures of bacteria. Attention is also directed to *In re Davis et al.*, 49 CCPA 1196; 305 F. 2d 501; 1962 CD 456; 783 OG 1244; 134 USPQ 256 which presented claims to vaccines containing both live and dead antigens of either viral or bacterial origin.

The Examiner in his answer appears to have considered the aspect of aggregation and also the "lack of invention" in the nutrient and preservative but to defeat the claims on this basis would require citation of pertinent prior art. We also note that claim 17 is for a single bacterium pre-

8a

served in the stated form rather than for a mixture of different bacteria.

The rejection of the foregoing claims on the basis advanced by the Examiner cannot be sustained.

The decision of the Examiner is reversed.

REVERSED

BOARD OF APPEALS

/s/ N. A. ASP
Examiner-in-Chief

/s/ H. MAGIL
Examiner-in-Chief

/s/ ARTHUR H. BEHBENS
Examiner-in-Chief

Woodhams, Blanchard and Flynn
2026 Rambling Road
Kalamazoo, Michigan 49001

9a

UNITED STATES PATENT OFFICE

3,642,982

Patented Feb. 15, 1972

UTILIZATION OF LIVING BACTERIA AS
INSECTICIDES

ROKUYA MORIMOTO, NEYAGAWA, and REIJIRO KODAMA, Toyonaka, Japan, assignors to Takeda Chemical Industries, Ltd., Osaka, Japan

No Drawing. Continuation-in-part of application Ser. No. 341,436, Jan. 30, 1964. This application Aug. 2, 1965, Ser. No. 476,682

Claims priority, application Japan, Feb. 2, 1963,
38/5,234; Aug. 6, 1964, 39/44,997
Int. Cl. A01n 15/00

U.S. Cl. 424—93

9 Claims

ABSTRACT OF THE DISCLOSURE

Alkalophilic and acid-producing bacteria—*Serratia piscatorum*, *Streptococcus faecalis*, *Aerobacter aerogenes*—are cultured to produce living cells which are useful insecticidally, more especially against lepidopterous larvae, such as common cabbage worm, etc.

• • • • •

What Is Claimed Is:

1. An insecticidal composition containing living bacteria consisting essentially of an inert insecticidal carrier and *Serratia piscatorum* ATCC No. 17999 or *Streptococcus faecalis* ATCC Nos. 15335, 14336 and 19000, the living bacterium being present in an amount of 0.05 to 5 weight percent.

2. An insecticidal composition according to claim 1, wherein the carrier is the culture medium in which the bacterium was grown.

3. An insecticidal composition according to claim 1, wherein the carrier is the dried culture medium in which the bacterium was grown.

4. The composition of claim 1, wherein the living cells are cells of *Serratia piscatorum* Breed ATCC No. 17999.

5. The composition of claim 1, wherein the living cells are cells of *Streptococcus faecalis* Andrews and Horder ATCC No. 15335.

6. The composition of claim 1, wherein the living cells are cells of *Streptococcus faecalis* Andrews and Horder ATCC No. 15336.

7. The composition of claim 1, wherein the living cells are cells of *Streptococcus faecalis* Andrews and Horder ATCC No. 19000.

• • • • •

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :
DALE E. BORDT ET AL :
Serial No. 700,251 : Group Art Unit 125
Filed: June 25, 1976 : Examiner: S. Rosen
For: DIPLOID PORCINE EMBRYONIC CELL STRAINS, CULTURES
PRODUCED THEREFROM, AND USE OF SAID CULTURES FOR
PRODUCTION OF VACCINES

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

AMENDMENT

Responsive to the Office Action mailed May 31, 1977,
please amend the above-identified application as follows:

IN THE CLAIMS

— 3 (Twice amended). A diploid porcine embryonic cell strain characterized by:

- (A) freedom from
 - (i) specified viral contaminants as measured by cytopathology, hemadsorption, inclusion body [straining] staining, and fluorescent antibody techniques,
 - (ii) specified bacterial contaminants as measured by sterility testing,
 - (iii) mycoplasma contamination as measured by brothagar subculturing;
- (B) nontumorigenicity in immunologically depressed hamsters;

(C) possessing a substantially constant degree of viral susceptibility;

(D) capable of maintaining substantial diploidy and not becoming senescent after at least 36 sub-culturings, while remaining free from morphological transformation and chromosomal anomalies; and

(E) retention of marker chromosomes[.] ;

and a suitable culture medium therefor.—.

REMARKS

The Examiner is thanked for the telephone interview courteously granted Applicants' attorney on June 13, 1977. Based upon the helpful suggestions of the Examiner Claim 3 has been amended and independent Claim 14 has been added.

The Examiner is thanked for citing the Green reference "to show a type of cell claim which may be found allowable." It is believed that Applicants' amendment of Claim 3 obviates the rejection of Claims 3, 5, 9 and 11 (and newly independent Claim 14) based upon the Examiner's allegation that, prior to the present amendment, they were "directed to nonstatutory subject matter (35 USC 101)." With the Green reference "type of cell claim" in mind, and based upon the Examiner's suggestion during the telephone interview, Applicants have amended Claim 3 to recite that their novel diploid porcine embryonic cell strain is in "a suitable culture medium therefor." Support for his added language is found, for example, on page 2, lines 3-4; page 4, lines 7-10; page 4, line 29; page 5, line 3; page 7 *et seq.* (note particularly the examples which recite culture media) of the specification.

UNITED STATES PATENT

4,166,112

Aug. 28, 1979

MOSQUITO LARVAE CONTROL USING A BACTERIAL LARVICIDE

Inventor: *Leonard J. Goldberg, Albany, Calif.*

Assignee: *The United States of America as
represented by the Secretary of the Navy,
Washington, D.C.*

Appl. No.: 888,083

Filed: Mar. 20, 1978

*Int. Cl.*² *A01N 15/00*

U.S. Cl. 424/93

Field of Search 424/93

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OTHER PUBLICATIONS

L. J. Goldberg, Chemical Abstracts, 82:150459p, (1975), Mortality of *Culex tarsalis* mosquito larvae obtained in laboratory studies using various combinations of *Bacillus thuringiensis* (HD-1) with two growth regulators.

N. T. Mirov, Chemical Abstracts, 46:3775i, (1952), Simmondsia or jojoba-a problem in economic botany.

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ABSTRACT

A method of controlling mosquito larvae, by using a spore-forming bacillus ONR-60A obtained from screening clonal isolates from soil samples of known mosquito larval breeding sites. A larvicide comprising the bacillus and a carrier is formulated as a buoyant colloidal suspension which stabilizes just under the surface of the water to concentrate in the feeding zone of many varieties of mosquito larvae.

7 Claims, No Drawings

• • • • •

What Is Claimed Is:

1. A bacterial larvicide active against mosquito-like larvae comprising:

(a) an effective larva killing concentration of spores of the pure biological strain of *Bacillus thuringiensis* var WHO/CCBC 1897 as an active ingredient; and

(b) a carrier.

2. A bacterial larvicide as recited in claim 1 wherein said spores and said carrier when mixed have the properties of a buoyant colloidal suspension.

3. The composition of claim 2 wherein said carrier comprises:

(a) dioxane; and

(b) a non-mineral, bio-degradable oleaginous liquid.

4. The composition of claim 3 wherein the admixture of the said spores and the said carrier forms a buoyant colloidal suspension just below the surface of the water in the feeding zone of mosquito-like larvae upon addition of water to said admixture.

5. The composition of claim 4 wherein said oleaginous liquid has specific gravity less than one.

6. The composition of claim 4 wherein said oleaginous liquid has hydrophilic properties.

7. The composition of claim 4 wherein said oleaginous liquid is jojoba oil obtained from the jojoba plant.

PATENTS TO LIVING SUBJECT MATTER

Re. 28,488	Farr	Reissued July 22, 1975
141,072	Pasteur	July 22, 1873
899,155	Coates	Sept. 22, 1908
952,418	Collett et al.	Mar. 15, 1910
1,099,121	Earp-Thomas	June 2, 1914
1,120,330	Odle	Dec. 8, 1914
1,178,941	Palma	April 11, 1916
1,260,899	Harris et al.	Mar. 26, 1918
1,442,239	Stoltz	Jan. 16, 1923
1,457,097	Whitmore	May 29, 1923
1,540,951	Reichel et al.	June 9, 1925
1,758,937	Earp-Thomas	May 20, 1930
1,851,165	Farr	Mar. 29, 1932
1,894,135	Torok et al.	Jan. 10, 1933
1,899,817	Matt	Feb. 28, 1933
1,957,555	Reichel et al.	May 8, 1934
1,989,014	Mazzucchi	Jan. 22, 1935
2,027,374	Fowler	Jan. 14, 1936
2,096,377	Loughlin	Oct. 19, 1937
2,098,918	Hendrickson	Nov. 9, 1937
2,121,442	Nordsiek	June 21, 1938
2,151,364	Winegarden	Mar. 21, 1939
2,262,851	Lescarbours	Nov. 18, 1941

2,268,955	Meier	Jan. 6, 1942
2,809,112	Anderson et al.	Oct. 8, 1957
2,919,194	Johnston	Dec. 29, 1959
3,072,528	Kludas et al.	Jan. 8, 1963
3,113,066	Emond	Dec. 3, 1963
3,150,062	Greenberg et al.	Sept. 22, 1964
3,184,384	Whalen	May 18, 1965
3,192,116	Mose et al.	June 29, 1965
3,228,840	Macpherson, et al.	Jan. 11, 1966
3,271,243	Cords et al.	Sept. 6, 1966
3,356,574	Smith	Dec. 5, 1967
3,360,440	Haab et al.	Dec. 26, 1967
3,364,117	Smith	Jan. 16, 1968
3,369,969	Nouvel	Feb. 20, 1968
3,420,742	Farr	Jan. 7, 1969
3,627,877	Ottens	Dec. 14, 1971
3,632,747	Ibuki et al.	Jan. 4, 1972
3,642,982	Morimoto et al.	Feb. 15, 1972
3,651,215	Ibuki et al.	Mar. 21, 1972
3,655,873	Duffy	Apr. 11, 1972
3,683,068	Forgacs et al.	Aug. 8, 1972
3,683,550	Corlett, Jr., et al.	Aug. 15, 1972
3,709,782	Smith et al.	Jan. 9, 1973
3,729,554	Suzuki et al.	Apr. 24, 1973

3,840,670	Holt	Oct. 8, 1974
3,849,551	D'Antonio	Nov. 19, 1974
3,855,121	Gough	Dec. 17, 1974
3,911,110	Smirnoff	Oct. 7, 1975
3,923,601	Treichler et al.	Dec. 2, 1975
3,935,066	Apostolov	Jan. 27, 1976
3,936,354	LaPointe et al.	Feb. 3, 1976
3,953,291	Chibata et al.	Apr. 27, 1976
3,960,664	Olsen et al.	June 1, 1976
3,984,575	Farr	Oct. 5, 1976
3,999,973	Templeton	Dec. 28, 1976
4,003,789	Green	Jan. 18, 1977
4,020,006	Parker	Apr. 26, 1977
4,061,488	Mann	Dec. 6, 1977
4,070,453	Eordt et al.	Jan. 24, 1978
4,138,292	Chibata et al.	Feb. 6, 1979
4,138,498	Das	Feb. 6, 1979
4,147,773	Ogasa	Apr. 3, 1979
4,161,084	Arny et al.	Jul. 17, 1979
4,166,112	Goldberg	Aug. 28, 1979
4,172,127	Huber	Oct. 23, 1979

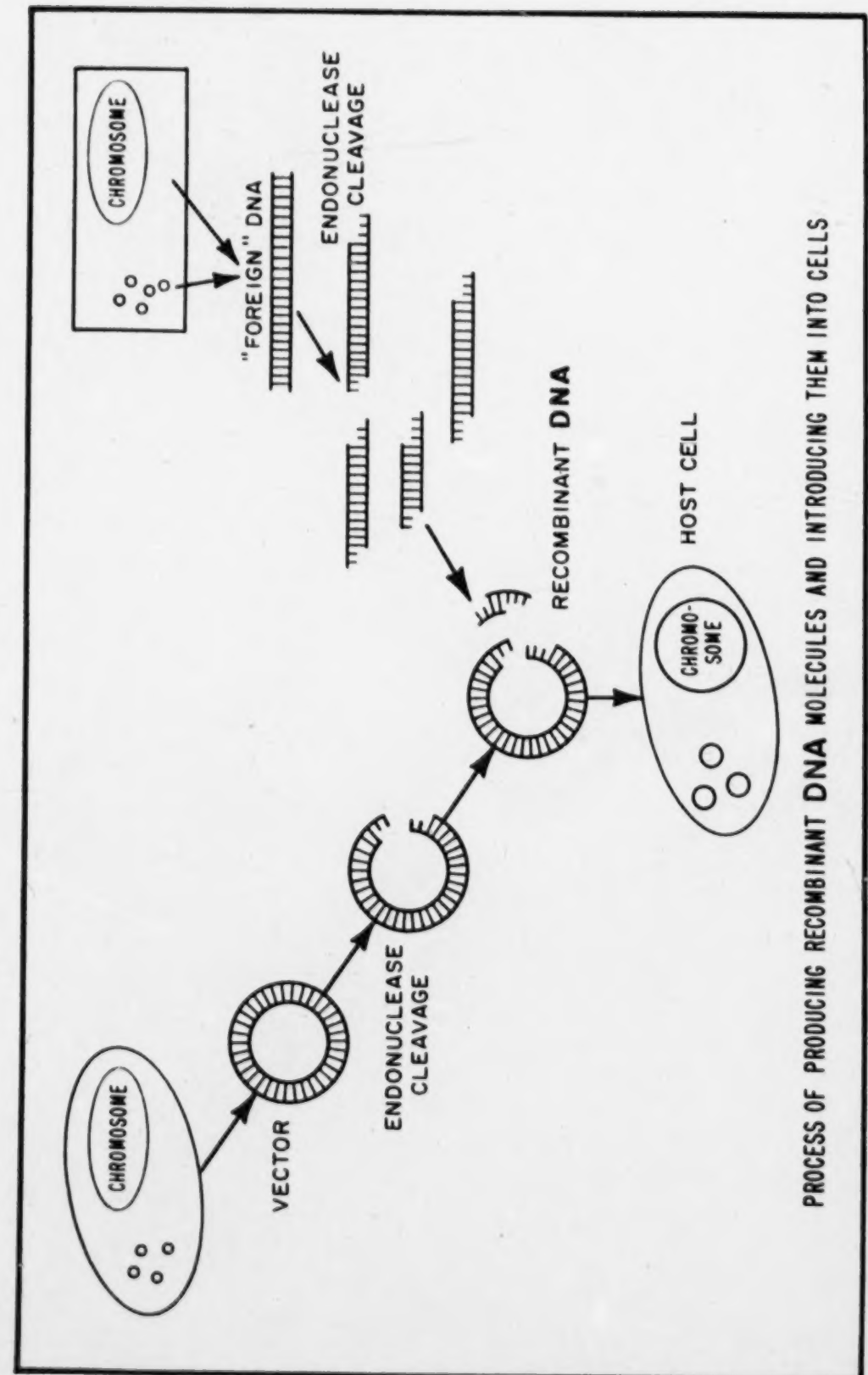
"The process of producing recombinant DNA molecules and introducing them into cells is illustrated in the drawing on the opposite page.

The cell represented at the upper left contains chromosomal DNA and several separately replicating DNA molecules. The nonchromosomal DNA molecules can be isolated from the cell and manipulated to serve as vectors (carriers) for DNA from a foreign cell. Most DNA molecules used as vectors are circular. They can be cleaved, as shown, by enzymes (restriction endonucleases) to yield linear molecules with rejoinable ends.

At the upper right is another cell, represented here as a rectangle. It serves as the source of the foreign DNA to be inserted into the vector. This DNA can also be cleaved by enzymes. The rectangular cell could be derived from any living species, and the foreign DNA might contain chromosomal or nonchromosomal DNA, or both.

In the next steps, the foreign DNA fragment is mixed and combined with the vector DNA, and the recombinant DNA is reinserted into a host cell. In most experiments this host cell will be of the same species as the source of the vector. The recipient cells are then placed under conditions where they grow and multiply by division. Each new cell will contain recombinant DNA.

Recombinant DNA technology represents a method that is applicable to many areas of biological research. Essentially, it represents a new tool. Investigations supported by many NIH Institutes and programs utilize this technique, much as a new instrument is applied in studying many different things." Proposed Revised Guidelines, Recombinant DNA Research, Friday, July 28, 1978, 40 Fed. Reg. 33101, 33102.



MAR 12 1980

No. 79-136

MICHAEL RODAK, JR., CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1979

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, PETITIONER

v.

ANANDA M. CHAKRABARTY

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEALS

REPLY BRIEF FOR THE PETITIONER

WADE H. MCCREE, JR.
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CITATIONS

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<i>Eibel Process Co. v. Minnesota & Ontario Paper Co.</i> , 261 U.S. 45	10
<i>Funk Brothers Seed Co. v. Kalo Inoculants Co.</i> , 333 U.S. 127	4, 5
<i>Gottschalk v. Benson</i> , 409 U.S. 63	4
<i>Parker v. Flook</i> , 437 U.S. 584	3, 9

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35 U.S.C. 163	10
37 C.F.R. 1.196(b)	2
37 C.F.R. 1.196(d)	2

Miscellaneous:

Chakrabarty, <i>Genetic Fusion of Incompatible Plasmids in Pseudomonas</i> , 70 Proc. Nat'l Acad. Sci. 1641 (1973)	11
Chakrabarty, <i>Genetic Regulation of Octane Dissimilation Plasmid in Pseudomonas</i> , 70 Proc. Nat'l Acad. Sci. 1137 (1973) ..	11

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REPLY BRIEF FOR THE PETITIONER

Respondent and his Amici contend primarily that it has long been a recognized practice in the Patent Office to grant patents on living organisms; that this Court should, as a matter of policy, interpret the Act to include living things, leaving it to Congress to exclude them expressly from the statute if it deems that desirable; and that the plain language of 35 U.S.C. 101 includes living things, and the legislative history

of the Plant Patent and Plant Variety Protection Acts does not suggest otherwise.¹ None of the contentions has merit.

1. In contrast to the position of amicus American Patent Law Association (Br. 23), Chakrabarty argues that "[p]revious Patent Office policy has been to grant patents on living things, and specifically on bacteria" (Resp. Br. 12; 12-25). He is wrong.

As proof of his assertion, respondent produces a list of 68 "patents claiming living subject matter"

¹ Amici Hood, *et al.* contend in addition that the case should be remanded for further consideration of whether the bacterium here is a product of nature, or, in the alternative, that the writ of certiorari should be dismissed as improvidently granted (Hood Br. 10-12). They claim that the patent examiner rejected the application solely on a "product of nature" rationale and that when the Board overturned this ground and rejected the claims because drawn to nonstatutory subject matter of living things, it violated a governing regulation (37 C.F.R. 1.196(d)) by not returning the application to the examiner for amendment (Hood Br. 10 & n.8). Amici are doubly wrong. The examiner based his rejection on two separate grounds: that the claims were to a product of nature, and that the claims were "not within the classes of subject matter patentable under section 101" (Pet. App. 166a). The Board reversed the first ground but affirmed the second. Moreover, even if "product of nature" were the only ground for the examiner's rejection, the Board still followed its regulation. The regulation permits the applicant to "waive such reconsideration before the primary examiner and have the case reconsidered by the Board of Appeals upon the same record before them." 37 C.F.R. 1.196(b). Chakrabarty chose this course and sought reconsideration before the Board (Pet. App. 168a-169a; Ct. of App. Rec. 97-113), thus waiving whatever rights he may have had to reconsideration before the examiner. There is thus no procedural defect in this case, and no basis for a remand or for dismissal of the writ as improvidently granted.

issued by the Patent Office from 1873 to the present (Resp. Br. 18; Resp. Br. App. 16a-18a). Whatever 68 such patents issued by examiners without review in more than a century might prove in the way of administrative practice, Chakrabarty's list is vastly inflated. We have examined each of the listed patents, and only three of the 68 clearly claim a novel, living organism itself.² The great majority of these 68 patents identify known, pre-existing organisms generally incidental to a process, combination, medium, or inanimate component.³ Moreover, since this handful of patents was issued without review by the Board of Appeals or the Commissioner, it is particularly poor proof of agency practice.⁴

² These three patents, all issued since 1967, bear the numbers: 3,923,601; 3,356,574; and 3,364,117. Six more, all issued since 1966, claim newly discovered microorganisms in an old medium, and thus involve a combination of a microorganism and non-living material (but cf. *Parker v. Flook*, 437 U.S. 584 (1978); Pet. 6 n.6). These are numbers: 3,228,840; 3,651,215; 3,683,068; 4,003,789; 4,070,453; and 4,166,112.

In addition, there are eight other patents of similar vintage which arguably claim a new living organism in combination with non-living material: 3,192,116; 3,632,747; 3,642,982; 3,709,782; 3,984,575; 4,138,498; 3,683,550; 3,935,066.

³ A summary of the early patents cited by respondent is attached as the Appendix, *infra*.

⁴ Contrary to respondent's assertion (Br. 19-20), the Board of Appeals in *Ex parte Farr* (Resp. Br. App. 6a-8a) did not rule that organisms in themselves are statutory subject matter. It had no occasion to do so, for Farr never claimed a novel strain of bacteria. Rather, he told the Board that the essence of his multi-step invention was "the use of additional ingredi-

Respondent's further contention (Resp. Br. 12-16) that the patents invalidated by this Court in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), and *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931), were on living things, rests on a misconception of the claims in those cases. The Court never considered the patentability of living things in those cases—and for very good reason. The Patent Office had not granted patents on living things because, unlike Chakrabarty, the inventors had made

ents, plus the concentration of the bacteria and the freezing" of his mixture (Br. before Bd. of App. 8).

That the Patent Office has a subclassification (No. 243) for "Microorganism Per Se" is not remarkable (cf. Resp. Br. 16-17). The category, established in 1979 mainly to conform to a uniform international convention proposed by the World Intellectual Property Organization, shows that, as everyone agrees, on rare occasions examiners have granted patents on specific living things. The failure of the Manual of Patent Examining Procedures to list living things in a group of examples of non-statutory subject matter (Resp. Br. 17-18) is not significant. The list claims no more than to provide some "examples" of non-patentable matter culled from "decisions." It omits non-patentable items such as algorithms. See *Gottschalk v. Benson*, 409 U.S. 63 (1972).

Finally, the 1959 letter from Commissioner Watson to Senator O'Mahoney (Resp. Br. 23) does not advance Chakrabarty's cause. In that letter, the Commissioner noted that patents are granted "on cultures and pharmaceuticals." S. Rep. No. 932, 86th Cong., 1st Sess. 7 (1959). Since no patents had yet been granted on new organisms per se (see note 2, *supra*), the Commissioner presumably referred to process patents where the use of "cultures" to produce "pharmaceuticals" was common or to patents such as those in the Appendix, *infra*.

no such claim.⁵ To be sure, the patents involved living things, but such involvement, as in a process patent (see Pet. Br. 38), is not necessarily an obstacle to patentability, because it is not a claim to the living thing itself. What makes Chakrabarty's claim significantly different and important is that he has claimed a specific organism itself.

2. Respondent (Br. 25-31) and his Amici (American Society for Microbiology Br. 7-11; Pharmaceutical Mfgs. Assoc. Br. 10-20; Genentech Br. 6-20; Piezenik Br.) suggest that it is desirable, as a policy matter, to issue patents for microorganisms, and that accordingly this Court should read Section 101 as permitting the issuance of such patents, leaving to Congress the option of specifically excluding living organisms if it wishes to do so. Even if the desirability of permitting such patents were clear, this analysis is inconsistent with the Court's approach to Section 101, as we discuss in our main brief (at 12). But the question of whether, and to what extent, living things should be patentable is far from clear, as the briefs

⁵ In *Funk Brothers* the claim was to the discovery that "well-recognized" strains of bacteria could be mixed together so that they did not inhibit each other in fixing nitrogen in plant roots. *Funk Brothers, supra*, 333 U.S. at 129 n.3. See Patent No. 2,200,532 (May 14, 1940). The inventor did not isolate or create any new organism. *Ibid*.

In *Brogdex* the inventors discovered that borax inhibits the growth of blue mold on orange skin. They claimed a process for impregnating the orange with borax and the resulting combination product of orange and borax. There was no claim to a new variety of orange.

of Amici themselves demonstrate (see, e.g., *Pieczenik Br.*; *Genentech Br.* 15-16).⁶

Respondent and Amici suggest that concerns over the risks of genetic engineering, like that involved in Chakrabarty's invention on the one hand and recombinant DNA research on the other, are exaggerated (e.g., *Resp. Br.* 25-27; *Genentech Br.* 10; *Pharmaceutical Mfgs. Assoc. Br.* 15-18). But Chakrabarty himself has recently recognized those hazards. See A. Chakrabarty & J. Brown, "Microbial Genetic Engineering By Natural Plasmid Transfer—Some Representative Benefits and Biohazards", reprinted in *Genetic Engineering* 185-193 (Chakrabarty ed. 1978). Thus, Chakrabarty frankly acknowledged that the

⁶ Amicus *Pieczenik* suggests that there is not always a clear distinction between the living and the non-living. In the present case and in many others, however, there can be no dispute on that question—the microorganisms resulting from Chakrabarty's work are alive. When and if closer cases arise, it will be incumbent on the courts or Congress to develop appropriate standards to decide them—just as courts and legislatures have recently found it necessary to consider the effects on the definitions of homicide and death of new scientific knowledge and practices.

Genentech notes that the Patent Office has suspended the examination of patent applications on plasmids, and suggests that this case would be an appropriate vehicle to decide whether plasmids are patentable (*Genentech Br.* 16-17). We do not agree. Examination of the approximately 16 pending applications for patents on plasmids or genes was suspended until the instant case is finally decided because almost all of these applications also claim a microorganism per se. The Patent Office has taken no position on the patentability of plasmids or genes, an issue not now before the Court, and this Court should not act until the Patent Office has had an opportunity to study and decide the question.

hazard resulting from a possible "change of the local ecological balance due to the massive seeding with the multiplasmid organism that might be required to rapidly digest the oil spill" is "less simply disposed of" than other claimed hazards (*id.* at 190). He cautioned that "tests for acute toxicity" should be done before there was any large-scale manufacture of the multiplasmid microorganism. *Ibid.*⁷ Moreover, while the controversy over the hazards involved in recombinant DNA may not be as intense as it was two or three years ago, it is still cause for concern. See *Recombinant DNA Research; Proposed Actions Under Guidelines*, 44 Fed. Reg. 69234, 69241-69245 (1979); *Krimsky & Ozonoff, Recombinant DNA Research: The Scope and Limits of Regulation*, 69 Am. J. Pub. Health 1252, 1257 (1979).⁸

⁷ Chakrabarty also expressed some concern about the hazards involved in the development of hybrid strains of *E. coli* using his plasmid-transfer technique (*id.* at 192). He destroyed one such genetically-engineered organism because he anticipated it might have had an adverse effect if introduced into the human intestine. Wade, *Dicing with Nature: Three Narrow Escapes*, 195 Science 378 (1977).

⁸ Amicus *Genentech* argues (*Br.* 10) that "'worries about the dangers of genetic engineering have all but disappeared'" quoting a Harvard professor, Dr. Walter Gilbert. See "*Glamour Stock*" *Could Help Cancer Patients*, Los Angeles Times, Jan. 21, 1980, Part I, at 3, 16. Dr. Gilbert helped form, and is chairman of the scientific board of, Biogen S.A., a Swiss company that is attempting to exploit the commercial possibilities of genetic engineering (*ibid.*). He is thus hardly an impartial observer in the debate over the biohazards associated with genetic engineering developments.

In any event, there is still much controversy over the question of whether patents should be granted on organisms that result from genetic engineering (see Pet. Br. 20; Krimsky & Ozonoff, *supra*, 69 Am. J. Pub. Health at 1253). The Amici favoring respondent stress the beneficial results of genetic engineering research and the importance of encouraging that research through the availability of patent protection.⁹ But these policy arguments should be addressed to Congress, not this Court (see Pet. Br. 14-15, 20).

3. Respondents (Br. 37-42) and Amici (Hood Br. 18-19; Genentech Br. 22; Regents Br. 10-13; N.Y. Patent Law Association Br. 8-15) contend that Chakrabarty's invention is within the statutory language defining patentable subject matter since a living organism is either a "manufacture" or "composition of matter" (35 U.S.C. 101).

But Section 101 does not stand alone. The relevant statutory text includes both the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970. The terms of Section 101 are thus shaped by these Acts, and under traditional canons of statutory construction, the entire statutory scheme provides strong evidence that Section 101's general subject matter definition does not include living things. See Pet. Br. 21-23.

⁹ The suggestion that the inability to patent a living organism will seriously impede the development of the technology of genetic engineering overlooks the availability in appropriate circumstances of patents on the *process* by which the new organism is developed.

In any event, this Court has rejected a purely literalistic reading of Section 101.¹⁰ *Parker v. Flook*, *supra*, 437 U.S. at 588-589. See *In re Arzberger*, 112 F.2d 834, 847 (C.C.P.A. 1940). Nor does the ordinary understanding of these terms necessarily comprehend living organisms. Common parlance simply does not tell us whether, in creating a hybrid organism with changed characteristics from those of pre-existing organisms, Chakrabarty did or did not "invent or discover" a new "manufacture" or "composition of matter."

Moreover, other familiar terms and concepts of the patent law are not easily adapted to the patenting of living microorganisms that reproduce themselves. The microorganisms themselves presumably would not infringe the patent by reproducing (and thereby manufacturing themselves) without a license. And a human being who himself becomes infected, or whose plant or animal (or whose food, liquid, etc.) becomes infected, presumably also would not become an infringer merely by providing the medium in which the microorganisms propagate (at least if he does so unintentionally and takes reasonable measures to curb the growth of the infection—and does not use the microorganisms in any way). But the very fact that living organisms may reproduce in ways and places uncontrolled by the patentee or his licensees,

¹⁰ Although Amici Regents of the University of California argue that the plain language of Section 101 covers Chakrabarty's invention, they forcefully point out that the CCPA has repeatedly refused to accept this Court's interpretation of that Section and that the CCPA's rationale in this case is inconsistent with this Court's decisions (Br. 24-27).

and perhaps in profusion (see J.A. 62, 77), suggests that patent grants on the organisms themselves would be unprecedented in scope.¹¹

4. We have explained in our main brief why the Plant Patent Act cannot reasonably be considered to be based on the belief that plants were unpatentable under the general patent laws because they were products of nature (Pet. Br. 33-36). Significantly, Congress distinguished between plants found in nature and those created by plant hybridizers like Luther Burbank, but nevertheless concluded that a new statutory provision was necessary to protect the latter, which were clearly *not* products of nature. Respondent maintains, nonetheless, that, with respect to Burbank's work, "it apparently was concluded that insufficient change to the plant was caused by man (rather than nature) to make the new plant a manufacture" (Resp. Br. 44). No authority is cited for this proposition. Respondent simply suggests that, because the genetics of hybridization were not fully understood in 1930 and because, when a cross was made, the resulting hybrid was not predictable, the hybrid was somehow a product of nature (*ibid.*). But it has never been a requirement for patentability under the patent law that an inventor anticipate, or fully understand, his results. See, *e.g.*, *Eibel Process*

¹¹ Certainly the offspring of an organism that sexually or asexually reproduces itself are not "made" by man, in the ordinary sense of that term. Compare 35 U.S.C. 154 with 35 U.S.C. 163.

Co. v. Minnesota & Ontario Paper Co., 261 U.S. 45, 62-65 (1923).

Moreover, the plant hybridizer of that day as much obtained "exactly what he set out to obtain" (Resp. Br. 45) as did Chakrabarty.¹² We have already referred to Burbank's selection of certain varieties for crosses (Pet. Br. 33-34 n.40). Similarly, Thomas Edison (a founder of the General Electric Company, the assignee of Chakrabarty's patent application) developed in 1929 a new, hybrid variety of goldenrod from which he extracted rubber. The new plant was created by Edison from the deliberate, calculated cross of two known species. See B. Vanderbilt, *Thomas Edison, Chemist* 94, 285-295, 320 (1971). Yet, as far as can be determined, Edison, a prolific patentee, never sought a patent on his new hybrid. Instead, in a communication reprinted in the reports of the congressional committees, he urged passage of the Plant Patent Act to afford patent protection to the work of plant breeders like himself. H.R. Rep. No. 1129, 71st Cong., 2d Sess. 3 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 3 (1930).

¹² The course of Chakrabarty's own research with plasmids demonstrates that he engaged in considerable trial and error experimentation before he obtained the hybrid microorganism he now seeks to patent. See A. Chakrabarty & J. Brown, *supra*, at 188; Chakrabarty, *Genetic Fusion of Incompatible Plasmids in Pseudomonas*, 70 Proc. Nat'l Acad. Sci. 1641, 1642 (1973); Chakrabarty, *Genetic Regulation of Octane Dissimilation Plasmid in Pseudomonas*, 70 Proc. Nat'l Acad. Sci. 1137, 1138-1139 (1973).

CONCLUSION

For the foregoing reasons, and those stated in our opening brief, the judgment of the Court of Customs and Patent Appeals should be reversed.

Respectfully submitted.

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MARCH 1980

APPENDIX

PATENTEE DATE		SPECIFICATION, AMENDMENTS AND ABSTRACT; NATURE OF CLAIMS
141,072 Pasteur May 9, 1873	Improvement in the Manufacture of Beer and Yeast	Improved Process for obtaining pure yeast free from contaminating germs or disease, employing distinctive apparatus. Claims are for (1) method of obtaining pure yeast; (2) "yeast free from organic germs or disease." No particular strain of yeast claimed.
899,155 Coates September 22, 1908	Fertilizer	Process for sterilizing dried materials, such as bone phosphate, dried slack lime and potash salts, and then inoculating it with a pure culture of a beneficial bacteria. The novelty resides in the idea of using a "practically dry fertilizing material of such nature as will not injuriously affect the life of the micro-organism." Claims are for the dried fertilizer in combination with a micro-organism. No particular micro-organism claimed.
952,418 Collett et al. March 15, 1910	Dietetic Chocolate and Cocoa	Process for preparing chocolate or cocoa. The novelty resides in the idea of putting a "ferment" compound of micro-organisms or enzymes into finished cocoa and then <i>drying</i> it, instead of then <i>heating</i> it as in prior processes. See amendment of Nov. 23, 1909. Claims are for the process and for the product of the cocoa and ferments combined. No particular micro-organism claimed.

PATENTEE DATE		SPECIFICATION, AMENDMENTS AND ABSTRACT; NATURE OF CLAIMS
1,099,121 Earp-Thomas June 2, 1914	Means for Distributing Soil Bacertia	Substantially nitrogen-free soil also freed of weeds, seeds and harmful organisms but containing available carbonaceous matter and artificially inoculated with "beneficial soil bacteria." The novelty resides in the idea of <i>combining</i> sterile soil with the beneficial bacteria, as compared to prior methods that used soil that had not been first freed of harmful bacteria. See amendment of Dec. 12, 1912. No particular strain of bacteria claimed.
1,120,330 Odle December 8, 1914	Medicated Food Product	A process for producing a palatable and readily-stored medium for introducing beneficial bacteria into the human digestive tract. See September 12, 1914 amendment. A "suitably concentrated culture of the desired [lactic acid] bacilli," is combined with cream, and then frozen. The patent claims a food product "comprising a frozen confection containing a culture of lactic acid bacilli * * *." No new bacterium claimed.
1,178,941 Palma April 11, 1916	Preparation for Infecting Vermin With Disease	"[M]ethod of and a preparation for destroying vermin by administration of nitrates in conjunction with administration of pathogenic bacteria." The novelty resides in the use of nitrates in combination with the bacteria to ensure the effectiveness of the bacteria. See April 2, 1914 response of Palma. No particular bacteria claimed.

PATENTEE DATE		SPECIFICATION, AMENDMENTS AND ABSTRACT; NATURE OF CLAIMS
1,260,899 Harris, et al. March 26, 1918	Process for Compounding Germs With An Enveloping Protective Medium	Process for administering "living germs" by mouth and preserving "their vitality during their passage through the stomach." The novelty resides in the process of reducing the germs to "a dormant state" and then enveloping them "with an air and moisture excluding [inert] substance" such as petrolatum. No new strain of bacteria claimed.
1,442,239 Stoltz January 16, 1923	Composition of Matter	A fertilizer, consisting of "a mixture of finely ground marble or limestone, phosphate rock and organic humus mixed together in about equal parts by weight, and impregnated with nitrifying bacteria." The novelty apparently resides in the unique combination of materials. No particular bacterium claimed.
1,457,097 Whitmore May 29, 1923	Vaccine and Method of Preparing Same	Both a method for preparing a vaccine and the vaccine prepared using the method. The novelty resides in the method of "embalming" living bacteria by "attenuating and sedimenting" the living organism, drying it, and finally grinding it in oil to "discrete or separate and individually coat with oil the cells or organism". See Whitmore's response of April 2, 1920. One claim (#9) specifies a vaccine composed of "living anthrax bacilli suitably prepared, discreted, and suspended in neutral, sterile vegetable oil" but there is no claim to any novel microorganism.

PATENTEE DATE		SPECIFICATION, AMENDMENTS AND ABSTRACT; NATURE OF CLAIMS
1,540,951 Reichel June 9, 1925	Process of Growing Lactobacilli and the Product	"[P]rocess of growing lactobacilli * * * in a culture medium other than milk or whey with the object of obtaining an increased number of bacilli in the medium, and harvesting the growth in a compact ingesting volume or mass." The novelty is in the idea of using a culture medium other than the digesting milk or casein previously used to grow the lactobacilli. No particular strain of bacteria claimed.
1,758,937 Earp-Thomas May 20, 1930	Lactobacteria Product	"[F]luid oil product containing viable lactobacteria, suitable for implantation in the intestinal tract." The novelty resides in the use of an emulsion of a suitable oil and a suitable emulsifying agent that serves to prevent the culture from settling out of the carrier. No particular strain of bacteria claimed.

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MICHAEL RODAK, JR., CLERK

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Supreme Court of the United States
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Petitioner

v.

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v.

ANANDA M. CHAKRABARTY

**BRIEF ON BEHALF OF THE PEOPLES
BUSINESS COMMISSION, AMICUS CURIAE**

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ANANDA M. CHAKRABARTY

**BRIEF ON BEHALF OF THE PEOPLES
BUSINESS COMMISSION, AMICUS CURIAE**

**I. INTEREST OF THE AMICUS CURIAE
AND INTRODUCTION**

The Peoples Business Commission (PBC) is a non-profit educational foundation incorporated in the District of Columbia. PBC develops a wide range of educational materials designed to raise public awareness of emerging economic and technological trends within the United States and the impact these trends will have on the lives of the citizens of this country.

PBC has emerged as one of the nation's leading critics of the various biological technologies known as "genetic engineering." It is the belief of PBC that the social application of genetic engineering is rapidly proceeding without due consideration or public understanding of the wide range of ecological, evolutionary, ethical, philosophical, political and economic questions inherent in any application of bio- and genetic manipulation.

Ted Howard and Jeremy Rifkin, co-directors of PBC, are co-authors of "Who Should Play God?," the largest selling book on genetic engineering. American high school and college professors are using this book as a standard text on the ethical and social implications of genetic manipulation. "Who Should Play God?" has been translated into six foreign languages, including Japanese, French and Spanish. Howard and Rifkin's articles on various aspects of genetic engineering have appeared in *The Los Angeles Times*, *Newsday*, *The Progressive*, *The St. Louis Post Dispatch*, and scores of other publications. Because of their familiarity with the social implications of genetic engineering, PBC staff members have been called upon to testify before Congressional Committees, the National Academy of Sciences, the Department of H.E.W. Ethics Advisory Board, and the Eastern Virginia State Health Agency.

The interest of the amicus herein is PBC's belief that the present cases are of critical importance to the potential development and direction of the burgeoning genetic engineering industry. Most financial and scientific observers concur that during the coming two decades, genetic engineering technologies will have a profit potential and social impact akin to the development of transistors and computers during the past twenty years. PBC contends that a ruling in favor of life form patents in *Bergy* and/or

Chakrabarty would serve as a precedent in a host of related areas of genetic manipulation, most particularly in the field of recombinant DNA, or "gene splicing." Such a ruling would significantly contribute to the profit potential of the genetic industry, thus generating a greater momentum in research and development of genetic engineering technologies. This, in turn, will lead to the rapid proliferation of genetic techniques in the areas of energy, agriculture, medicine, industrial processes and many other aspects of the nation's economic life.

It is PBC's contention that such a proliferation of genetically-based technologies is not in the public interest for a host of reasons. PBC believes that the ecological, evolutionary, ethical, philosophical, political and economic questions that surround the patenting of living organisms have been given insufficient consideration by the Congress, the country as a whole and the lower court in issuing its ruling in favor of such patents.

All parties have consented to the filing of this *amicus* by letter, the originals of which are being filed concurrently with the clerk.

II. THE ISSUES PRESENTED

The issues addressed by this amicus are:

Whether genetically engineered forms of life are a "manufacture" or "composition of matter" intended by Congress to be subject to patentability within 35 U.S.C. 101.

Whether it is in the "public interest" and serves the "useful Arts" to patent living organisms.

III. STATEMENT OF FACTS

On March 29, 1979, the Court of Customs and Patent Appeals ruled that General Electric and Upjohn be granted the nation's first patent for genetically engineered forms of life. The General Electric life form, a *Pseudomonas* bacterium developed by Dr. Ananda M. Chakrabarty, contains a new combination of plasmids not previously found in nature. This microorganism produces enzymes which break down a number of the hydrocarbon components of petroleum. The Upjohn microorganism, *Streptomyces vellosus*, was isolated by Dr. Malcolm E. Bergy et al., and is used in a process to produce by fermentation the antibiotic lincomycin.

The two life form patents were granted under the provision of Section 101 of Volume 35 of the U.S. Code which reads: "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor. . ." In ruling in favor of the patent applications of the two companies, the majority held that there was no justification for excluding an "invention" merely "because it is 'alive'." The lower court further argued that "from the standpoint of construing the patent statutes, we do not see. . . *any sound reason* for making the distinction . . . here between the living and the dead."

The Patent and Trademark Office had refused to grant GE and Upjohn patents on living organisms because of its belief that Congress never intended that forms of life be patentable under 35 U.S.C. 101. The PTO argued that because "the number of living things is vast," the awarding of life form patents "opens an enormous range of subject matter to patentability" including "living organisms — life itself."

The Solicitor General of the United States petitioned this Court for a writ of certiorari. On 29 October of 1979, the Court granted the Solicitor's petition for writ of certiorari in *Parker v. Bergy et al.*

IV. SUMMARY OF ARGUMENT

The Solicitor General of the United States contends that the Congress of the United States never intended that living organisms, whether modified through genetic engineering or not, be patentable under 35 U.S.C. 101. We support the Solicitor on this point, and will not further argue it herein.

The arguments developed in this brief are three-fold:

1. That the single area in which Congress has specifically authorized the patenting of living organisms through legislation — the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 — provides ample evidence that the patenting of any form of life (plant or otherwise) necessarily leads to certain genetic and social impacts that are not in the best interests of society or succeeding generations.
2. That the technology of genetic engineering, taken as a whole, is not in the public interest, and should not be unduly encouraged by giving unwarranted economic incentive to corporations in the field of genetic research and development through the vehicle of awarding potentially lucrative patents on living organisms.
3. That if patents are granted on microorganisms there is no scientific or legally viable definition of "life" that will preclude extending patents to higher forms of life, and that, indeed, the various technologies of genetic engineering have already created a climate in which patents on

higher organisms can consistently be claimed once the precedent has been set with microorganisms.

V. ARGUMENT

1. THE RELATIVELY RECENT HISTORY OF GRANTING PLANT PATENTS ILLUSTRATES THE DELETERIOUS GENETIC AND SOCIAL EFFECTS OF PATENTING LIVING ORGANISMS.

Until the March 29, 1979 Court of Customs and Patent Appeals decision awarding patents on genetically engineered microorganisms to General Electric and Upjohn, the only living organisms considered patentable under Congressional legislation were certain types of plants and seeds. The history of our national plant patenting policy serves as a backdrop to the issue now before this Court, and should be given serious consideration before any decision regarding the patenting of other living organisms is reached.

In an attempt to encourage plant breeding and the development of new types of crops with desirable characteristics, Congress passed the Plant Patent Act of 1930. This Act provides for the patenting of certain types of *asexually* reproduced plants. Four decades later, Congress extended this legislation with the Plant Variety Protection Act of 1970, which provides for, among other things, certificates akin to patents for certain kinds of *sexually* produced plants.

These acts were passed on the assumption that patents would provide the economic incentive that would lead to the production of numerous man-made plant varieties that would be of social benefit. In fact, just the opposite has taken place. According to a publication of the National Sharecroppers Fund, the genetic and social consequences

of global plant patent laws pose "a serious threat to world food supplies and to the future of agriculture."¹

The deleterious effects of the various plant patent laws have been three-fold:

First, the availability of plant patents has led to the systematic, and irreversible, elimination of many varieties of useful plants and crops simply because they were products of nature and thus could not be patented. Because of this basic economic fact of life, seed and grain companies encourage the world's farmers to buy their "superior" products rather than using naturally existing native strains. Convinced of the 'superior' qualities of newly bred and designed varieties of crop plants, farmers cease to grow their traditional crops. Writes Cary Fowler of the Frank Porter Graham Demonstration Farm and Training Center of Wadesboro, North Carolina, "leftover seeds of the traditional variety may be used as food for the family or their animals. In a moment's time, thousands of years of crop development and seed selection become meaningless and another variety becomes extinct."² *Thus, as a direct result of plant patent legislation, thousands of useful varieties of plants have been eliminated from the planetary gene pool.*

Second, and as a corollary to the first effect, as patentable plants have been widely propagated, and nonpatentable varieties have been eliminated, genetic diversity is lost, and monoculturing becomes the rule. Again, Fowler: "Modern agriculture needs predictability; therefore, plant breeders strive for uniformity. Plants are bred and inbred to develop the desired characteristics. The result has been

¹Cary Fowler, *The Graham Center Seed Directory*, Rural Advancement Fund of the National Sharecroppers Fund, (Wadesboro, North Carolina: 1979).

²*Id.*

the creation of new varieties that are extremely genetically limited. . . . Where thousands of varieties of wheat once grew, only a few can now be seen. When these traditional plant varieties are lost, their genetic material is lost forever. Herein lies the danger. Each variety of wheat, for example, is genetically unique. It contains genetic 'material' not found in other varieties. If, because of genetic limitations which result from inbreeding, new varieties are no longer resistant to certain insects or diseases (conceivably even insects or diseases never before known to attack wheat), then real catastrophe could strike."³

In fact, due to the elimination of genetic diversity stemming from the patentability of certain types of plants, disaster has already struck many farmers. The monocultured sugarcane industry has nearly been wiped out twice, and the banana industry has similarly been threatened due to lack of genetic diversity. In 1970, a corn blight struck the U.S. crop. Nearly 15 percent of the nation's crop was destroyed; in some southern states the losses topped 50 percent. According to the National Academy of Sciences: "The key lesson of 1970 [the year of the corn blight] is that genetic uniformity is the basis of vulnerability to epidemics. [Today] . . . most crops are impressively uniform genetically and impressively vulnerable."⁴ According to a National Academy of Sciences study, just one type of sweet potato produces 69 percent of our domestic crop; two varieties of dry beans yield 60 percent of our crop; three types of millet, 100 percent; 6 types of corn, 71 percent.⁵ *Again, the internal logic*

³*Id.*

⁴Committee on Genetic Vulnerability of Major Crops, *Genetic Vulnerability of Major Crops*, National Academy of Sciences, 1972.

⁵Committee on Germplasm Resources, *Conservation of Germplasm Resources*, National Academy of Sciences, 1978.

of plant patenting has led directly to the loss of genetic diversity and the reliance of societies upon dangerously inbred and frail monocrops.

The third effect of the Plant Patent Act is not genetic, but rather social. In a report recently published by the London-based International Coalition for Development Action, "Seeds of the Earth," author P.R. Mooney outlines how plant patent legislation has made plant breeding such a lucrative endeavour that ownership of the world's basic plant food supply is increasingly being concentrated within a small number of large multinational corporations. Seventy-nine percent of the U.S. patents issued on beans have gone to just four companies, and nearly fifty once-independent seed companies have recently been acquired by corporations such as ITT, Upjohn, Purex, and so on. According to the ICDA report, these large companies build up private gene banks to which access is limited to the companies' plant breeders. Once again, thanks to the patent laws, the bulk of the world's food supply is now owned and developed by a handful of corporations which alone, without any public input, determine which strains are used and how. ICDA claims: "in some crops a single enterprise dominates the total world germplasm holdings." United Brands, for instance, privately possesses two-thirds of the world's banana germplasm in storage.⁶

This three-fold trend — the loss of genetic diversity, monoculturing of disease and pest susceptible crops, and the private manipulation of food resources that properly belong to the entire family of man — continues unabated. In Europe, an alarming escalation of this momentum is taking place. Because living organisms such as plants

⁶P.R. Mooney, "Seeds of the Earth," International Coalition for Development Action, (London: 1979).

change genetically in subtle ways in response to their environment, companies have been confronted with the difficulty of enforcing their patents on "products" which differ from year to year. In an attempt to reduce these problems, legislation approved by Common Market member countries will, by 1981, make thousands of plant varieties now commonly grown in Europe *illegal*. These varieties can no longer be grown commercially; their seeds can not be sold; backyard gardeners can be fined for growing the banned vegetables. According to Dr. Erna Bennett of the Food and Agricultural Organization of the United Nations, up to three-quarters of all vegetable varieties now grown in Europe will go extinct as a result of this legislation. "Genetic wipe-out," she says, "might well be tomorrow's greatest single problem. . . ."⁷

Because of these alarming developments, the International Coalition for Development Action recommends that patent laws in all countries relating to plants should be uniformly repealed, and plants should be recognized as "resources of common heritage to all peoples."⁸

The history of the results of the several plant patent acts clearly shows that far from leading to a multiplicity of social benefits, the patenting of plants has in fact cruelly robbed succeeding generations of their own right to a diversified, healthy and vital gene pool. We have, in effect, made an irreversible choice for all those humans yet to be born.

Because plants are the only living organisms now patentable, the above mentioned consequences of plant patent-

⁷Cary Fowler, "From Patented Seeds, Big Business Grows," *ruralamerica*, September 1979.

⁸Mooney. See also: "To Promote the Progress of . . . Useful Arts," *Report of the President's Commission on the Patent System* (1966) at 13, 14; *Gottschalk v. Benson*, 409 US 63 at 72, 73.

ing must be seriously considered as a possible pattern that may be repeated should other forms of life be deemed patentable by this Court. The lessons so harshly learned from plant patenting are particularly applicable in the following areas of genetic engineering:

* The novel microorganisms that will be created through various genetic engineering techniques may well be, in many cases, "superbugs," that is, they will be bred or engineered in such a way that they may become the dominant form of life within their niche in the ecosystem. The General Electric *Pseudomonas*, for instance, is acknowledged to contain properties resulting from the combination of a number of other bacterium. Once these microorganisms are unleashed into the ecosystem, on purpose or by accident, they may out compete other forms of life because of their unique properties. This could seriously damage the vitality of the gene pool.

* The monoculturing of certain types of high-yield, but disease and pest susceptible plants, will be repeated by the genetic engineering industry through the monoculturing of "superior" microorganisms. Geneticists are currently predicting, for instance, that within the near-term future, various chemicals, hormones and drugs will be solely produced in the laboratory by genetically engineered microorganisms because such techniques are "cost-effective." Thus, within the foreseeable future, the world will be dependent upon a very limited number of biological entities to produce vital medicine and chemical necessities. The monoculturing of microorganisms may well prove as deficient as that already acknowledged in food crops.

* If patents are extended to genetically modified higher organisms (such as domestic livestock) — and we will argue later in this brief that the awarding of

microorganism patents sets a dangerous precedent for this occurrence — there can be little doubt that the full history of the patenting of plants will be repeated. One can anticipate that a small number of cattle genotypes will be widely reproduced because of their “superior” characteristics; other, less useful, cattle will become extinct; the diversity of the animal gene pool will be as narrowly defined as that now existant among corn, wheat and so on. Dr. Clement Markert of Yale, for instance, is working on methods for the asexual production (cloning) of domestic livestock such as cattle and sheep. In *Fortune* magazine Dr. Markert was quoted as saying: “I could wipe out all of Yale’s deficits with the valuable bulls raised from the embryos I could produce in one weekend.”⁹ That may well be the case, but the fact remains that any such attempt will seriously and irrevocably disrupt the gene pool.

* Finally, the history of domestic plant patenting is particularly relevant to *Bergy* because many of the very same companies that have gained control of the world’s food germplasm are also those now engaged in microorganism genetic engineering. Upjohn, currently seeking the *Bergy* patent, is the owner of two major seed companies and their plant patents. As a result Upjohn and three other companies hold 79% of all bean patents, Upjohn and five other companies hold two-thirds of all patents issued for lettuce, and Upjohn shares with only one other company 43% of all the patents issued for peas. Other companies in similar positions include Pfizer, Ciba-Geigy and Monsanto.¹⁰ There is no reason to believe that these companies will develop the genetic engineering life form industry any

⁹Gene Bylinsky, “The Cloning Era is Almost Here,” *Fortune*, June 19, 1978.

¹⁰Cary Fowler, Testimony on behalf of The National Sharecroppers Fund, before the House Agriculture Subcommittee, July 19, 1979.

differently than they have already done in the area of patentable plants.

It is an accepted fact that a patent cannot be given for laws of nature, phenomena of nature, scientific principles or mathematical equations. Quoting from Rosenberg, “The reason is founded upon the proposition that in granting patent right, the public must not be deprived of any rights that it theretofore freely enjoyed.”¹¹ The history of the consequences of plant patent legislation indicates that because plants have been subject to patentability, the public has already lost a right which it once freely enjoyed — the right to a diversified gene pool composed of thousands of varieties of naturally occurring life forms. This basic right of our generation and most especially succeeding generations should not be even more greatly infringed upon by the awarding of patents on genetically engineered living organisms.¹²

2. THE TECHNOLOGY OF GENETIC ENGINEERING, TAKEN AS A WHOLE, IS NOT IN THE PUBLIC INTEREST.

The majority opinion in *Bergy*, October 6, 1977, held: “We think that it is in the public interest to include microorganisms within the terms “manufacture” and ‘composition of matter’ in 101.”¹³ Below, in an amicus brief supporting *Chakrabarty*, the American Patent Law

¹¹P. Rosenberg, *Patent Law Fundamentals*, (1975).

¹²All forms of life are the embodiment or epitomy of the laws of nature which this Court has repeatedly held are not patentable subject matter under 35 U.S.C. 101 and its predecessors, absent express Congressional authorization. See, e.g., *Parker v. Flook*, 437 U.S. 584, and cases cited therein.

¹³563 F.2d 1031. As reported in Solicitor General’s Petition for Writ of Cert. to Supreme Court, pp. 120a, 121a.

Association claims, "there can be no doubt that molecular biology and genetic engineering techniques constitute a 'useful art' in today's world."¹⁴ Other interested parties in these cases have made similar claims.

The question of whether the public will be well-served by the patenting of living organisms and the technology of genetic engineering should most properly be left to the public-at-large and its elected representatives. However, since the claims that genetic engineering is "in the public interest" and a "useful art" have been made by those who seek life form patents, and since these claims seem to be an implicit part of the debate over the granting of such patents, PBC cannot allow such assumptions to go unchallenged.

PBC contends that the granting of patents on living organisms and the flurry of research and development such patents will generate within the budding industry of genetic engineering are not in the public interest.

Few Americans are aware of the potential impact that the patenting of microorganisms, in particular, and the genetic engineering industry, in general, will have on their lives and their society. The term "Biological Revolution" has rightly been used to characterize the astounding and awesome strides being made in the fields of biology and genetics. Because of this Biological Revolution, highly technological societies such as ours are on the threshold of controlling the biological and genetic quality of all living material, from the humblest microorganism to the most proud human. As Dr. George Wald, the Harvard Nobel-laureate has said, "we are moving from the organic design of life to technological specification of living material."¹⁵

¹⁴At page 4.

¹⁵Cited in Ted Howard and Jeremy Rifkin, *Who Should Play God?*, (New York: Dell, 1977).

Just as we have manufactured metals and plastics, now there are those who contemplate manufacturing life itself.

This potential, to turn living material into yet another factor of economic production, has led many scientists and corporate officials to forecast a multi-billion dollar genetics industry hovering just over the horizon. Already, dozens of the nation's Fortune 500 firms — Standard Oil, General Electric, Upjohn, among them — along with a growing number of smaller, recently founded genetic companies — Cetus, Genentech, Genex, Biogen — are engaging in research which is expected to be of tremendous profit-making potential.¹⁶ A few quotes from company officials serve to illustrate the enthusiasm surrounding genetic engineering:

Gordon C. McKeague, corporate development manager for Standard Oil of Indiana: [Genetic technologies represent] "the growth business of the future."¹⁷

Nelson Schneider, investment analyst for E.F. Hutton: "The potential applications of this technology are revolutionary and incredibly broad. . ." Speaking of various types of genetic

¹⁶For basic information on the growth of the genetic engineering industry, see: Ted Howard, "Patenting Life," *The Progressive*, September, 1979; Jeremy Rifkin, Larry Gordon and Dan Smith, "DNA," *Mother Jones*, February-March, 1977; "Where genetic engineering will change industry," *Business Week*, October 22, 1979; "DNA is on the way to chemicals," *Chemical Week*, September 26, 1979; Sharon Begley, "The DNA Industry," *Newsweek*, August 20, 1979; Nelson M. Schneider, "DNA — The Genetic Revolution," E.F. Hutton Review, August 1, 1979; Nelson M. Schneider, "Biotechnology," E.F. Hutton, November, 1979; David Dickson, "Recombinant DNA research: private actions raise public eyebrows," *Nature*, vol. 278, 5 April 1979.

¹⁷Quoted in "Where genetic engineering will change industry," *Business Week*, October 22, 1979.

technologies, Schneider uses rhetoric including: "a major new profit opportunity. . . the most exciting investment potential . . . substantial growth possibilities. . ."¹⁸

Irving Johnson, vice president of research at Eli Lilly: "Potential applications of (genetic) techniques are limited only by the imagination of the people using them."¹⁹

A great deal of this profit making potential is based upon the controversial technique of recombinant DNA or "gene splicing." While neither the GE nor the Upjohn organism under consideration in this case are products of "gene splicing," the considered opinion of the great majority of scientists engaged in genetic engineering is that the granting of patents to GE and Upjohn here will be perceived by the industry as a signal that organisms generated through recombinant DNA will be patentable as well, since these microorganisms will be as much a "manufacture" or "composition of matter" as are the Bergy and Chakrabarty "inventions."

A reading of genetic industry literature, and personal interviews with many of the principals in the field of genetic engineering, leads PBC to conclude that during the coming decade, Americans will come in contact with genetic manipulation every time they drive their car, sit down to dinner, reach into the medicine cabinet, enter the hospital, or visit the neighborhood shopping mall. An E.F. Hutton investment publication, "Biotechnology," outlines genetic engineering research that is moving toward commercial

¹⁸Nelson M. Schneider, "Biotechnology," E.F. Hutton, November, 1979.

¹⁹Quoted in Nicholas Wade, "Recombinant DNA: Warming Up for Big Payoff," *Science*, Vol. 206, 9 November, 1979.

application including: the GE and Upjohn microorganism "products"; the potential for producing alcohol, ethylene glycol, plastic precursors and billions of dollars worth of chemicals, hormones, enzymes and drugs; and nitrogen fixation of plant crops.²⁰

It is arguable that such commercial applications of genetic engineering are in the public interest. Every "problem" deemed solvable through genetic engineering can, in fact, be tackled in numerous other ways. Oil spills can be consumed by GE's microorganism, for example, or Congress can legislate standards for oil tankers restricting their length and carrying capacity to a more manageable and navigable size. More important, alternatives to technologies based upon microorganisms are inherently safer ecologically, do not risk contamination of the gene pool, and do not carry with them the ethical implications of patenting life.

In short, in solving some social problems, genetic engineering will create others of a greater dimensional magnitude not yet understood by the general public. While it is true that every technology has adverse "side effects," the dangers posed by genetic engineering are of an irreversible nature. These dangers should therefore be recognized by the Court as important factors in any consideration of granting life form patents which will encourage industry to more rapidly develop genetic technologies.

Genetic engineering will, within the lifetime of many of us, give some individuals or institutions the final and awesome power to irreversibly violate three billion years of evolutionary wisdom through the creation of novel life forms, or the genetic alteration of living entities now existent. Humanity is about to become an active participant in

²⁰Schneider, "Biotechnology."

evolution through the use of this powerful technology, a process which will pre-determine for all succeeding generations the quality of the gene pool they inherit.

The most immediate danger to the public interest is that the proliferation of genetic engineering techniques and novel forms of life will irreversibly pollute the planetary gene pool in radically new ways. Dr. Jonathan King, a biologist at MIT, is one of a number of scientists who foresees tremendous "biohazard" problems emanating from the genetic industry. King points out that by developing novel forms of life through recombinant DNA, entities which do not now exist in the ecosystem, we run the risk of creating the ultimate in "pollution and disease disasters." According to King, as scientists and corporations join together to profit from the new life forms, they are completely discounting the fact that "there are no non-polluting technologies. With recombinant DNA, there will be a pollution of a new kind, biological pollution, pollution that grows as the organism reproduces itself. Yes, you could say that it's a renewable resource, but the pollution from it is renewable, too."²¹

The General Electric Company *Pseudomonas* may well be a case in point. GE hopes to one day unleash its microorganism on an oil slick, thus preventing a tanker spill from polluting the shoreline. Environmentalists, however, are voicing concern about where the "oil eater" will go once the petroleum is consumed. GE's test results indicate that in laboratory conditions the "bug" will die once its food supply is eaten. But what if natural conditions turn out to be more complicated than the laboratory

²¹Telephone interview with King. See also: Jonathan King, Ethan Signer, Stuart Newman, and David Ozonoff to Dr. John Nutter, NIH, May 15, 1979 (documents 685 and 686, Office of Recombinant DNA Activities, NIH).

controlled environment? Or what if the genetic industry follows the standard operating procedure of petrochemical firms which are known to churn out tens of thousands of synthetic organic chemical compounds annually, but only test a handful to determine if they are carcinogenic or mutagenic? We are just now witnessing the horrific effects of PCBs, dioxin, and other compounds that went untested in the rush to the market. In a genetic accident, the price will be much higher. Once out of the laboratory, there is no recalling a life form.

Disease and pollution scenarios are no mere conjecture. Recently conducted experiments concerning the safety of recombinant DNA have proven the biohazard potential of such a technique. According to Francine Simring of the Coalition for Responsible Genetic Research, NIH-sponsored research has demonstrated that: (1) gene-splice products cause tumors in experimental mice; (2) naked polyoma (multiple tumor) DNA causes infection; (3) novel microorganisms that escape the laboratory can survive for some four days in the human gut and in sewage.²² Dr. Stuart Newman of New York Medical College points to experiments that indicate that "quantitatively new routes of dissemination" of cancer-causing agents can result from certain types of recombinant DNA research.²³

²²Francine Simring, "Guidelines out the Window?" *Not Man Apart*, October 1979.

²³Stuart Newman, *Federal Register*, vol. 44, No. 213 (November 1, 1979): 63075, 63076. For further material on biohazard possibilities, see: Stuart Newman, letter to *Nature* 281 (20 September 1979); Nicholas Wade, "Recombinant DNA: A Critic Questions the Right to Free Inquiry," *Science* Vol. 194 (15 October 1976); *CRGR Newsletter*, Coalition for Responsible Genetic Research, New York, September 1979; Judith Randal, "All the Way with DNA?" *Medical Dimensions*, April, 1978; George Wald, "The Case Against Genetic Engineering," *The Sciences*, September-October, 1976; Liebe Cavalieri, "New Strains of Life — or Death?" *New York Times Magazine*, August 22,

What makes these issues of potential biohazard and gene pool disruption so critical at this time is the fact that there is absolutely no governmental regulation of industrial genetic engineering research and development. The quest for life form patent rights has had inhibiting effects on the development of Federal safety standards to regulate genetic engineering experimentation (specifically, recombinant DNA). The assertion by numerous companies that safety guidelines can not be monitored or enforced by the government without compromising corporate proprietary information has led the National Institutes of Health to conclude that privately funded genetic research need be subject to only voluntary compliance with already existing Federal safety standards. It is a known fact that companies are not now complying voluntarily with these standards. One genetic engineering firm has gone so far as to publicly flaunt its violation of NIH guidelines.²⁴

At this stage of development, and by all indications the situation is not likely to change, the public-at-large has absolutely no control over which genetic technologies are developed, how they are developed, or how they will be

1976; Robert Sinsheimer, "An Evolutionary Perspective for Genetic Engineering," *New Scientist*, January 20, 1977; Frances R. Warshaw, *Gene Implantation: Proceed with Caution*, Science for the People, Boston, November, 1976.

²⁴For an overview of Federal attempts to regulate genetic engineering research, see: Susan Wright, "Recombinant DNA Policy: From Prevention to Crisis Intervention," *Environment* vol. 21, No. 9 (November 1979); Katherine Ellison, "Firm Pushes Ahead in Genetics," *The Washington Post*, July 5, 1979; Nicholas Wade, "Major Relaxations in DNA Rules," *Science* Vol. 205, 21 September, 1979; David Dickson, "US expected to exempt most recombinant DNA experiments from federal regulation," *Nature*, vol. 281, (13 September 1979); "NIH Proposes new DNA rules for Industry," *Chemical Week*, August 9, 1978. For a history of NIH policy-making on recombinant DNA, see *Environment* (May 1978), pp. 6-15 and 39-41; and *Environment* (April 1979), pp. 2-5.

applied. Indeed, at this point, while science now knows enough to create new forms of life and disrupt the evolutionary process, no one can really foresee the impact these technologies will have on the ecosystem, the biosphere and the quality of the gene pool. There are many questions that simply cannot be asked because there has been insufficient time to consider all of the possibilities. The 'technological fix' has become the rule in this field: "if it can be done, then it should be done."

If the lower court ruling is upheld, and patents on living organisms are awarded to General Electric and Upjohn, all chance of meaningful public education and participation in the policy decisions surrounding genetic engineering will be lost, for the granting of patents is sure to escalate the drive toward commercial application. The genie will be out of the bottle before most Americans have even realized that the bottle was uncorked.

It is true that all technologies have their unanticipated costs. Society recognizes these costs as part and parcel of the price of technological innovation, and generally applies cost/benefit analysis to new techniques. However, cost/benefit analysis cannot be used in judging genetic engineering, because the cost is of an ultimate nature — the pollution of the planetary gene pool — and will have to be borne by every human yet to come.

THE PATENTING OF LOWER ORGANISMS WILL INVARIABLY LEAD TO THE PATENTING OF HIGHER FORMS OF LIFE.

Beyond the biohazard and gene pool disruption potential of genetic engineering, lies a complicated web of intersecting moral, ethical and philosophical issues concerning the patenting of living organisms. PBC contends that there is no scientifically or legally viable definition of "life" that can preclude the patenting of higher forms of

life should the Court set a precedent by granting patent rights to microorganisms.

There is little doubt that if the science of genetic engineering had progressed sufficiently to the point where higher forms of life could be significantly modified, the entire issue of patenting living organisms would be viewed quite differently in this case. However, simply because the "state of the art" has not yet progressed to this point does not mean that this point won't be reached, and reached far sooner than most people expect. Scenarios which once appeared far-fetched — the manufacturing of mammals, including human beings, to specification; the creation of super-intelligent beings; the asexual reproduction of organisms through cloning; the advent of genetic surgery designed to alter the heredity of complex organisms — will become science fact, if not tomorrow, then certainly within the lifetimes of the majority of Americans.²⁵

²⁵For information on possible human applications of genetic engineering, see: Howard and Rifkin, *Who Should Play God?*, (New York: Dell, 1977); Ted Howard, "Laboratory Fertilization: Is it a First Step to Genetic Manipulation?" *St. Louis Post-Dispatch*, November 21, 1979; Ted Howard and Jeremy Rifkin, "Playing God in the Laboratory: The Politics of DNA Research," *Newsday*, January 25, 1978; Howard and Rifkin, "Cloning: If It's True, It's Truly Fantastic," *Los Angeles Times*, March 14, 1978; Ted Howard, "The Test-Tube Baby: Medical Triumph or Brave New World?" testimony presented before the Ethics Advisory Board of H.E.W., fall, 1978; Charles Frankel, "The Specter of Eugenics," *Commentary*, March, 1974; Jon Beckwith, "Social and Political Uses of Genetics in the U.S.: Past and Present," *Annals of the New York Academy of Sciences*, 265, 1976; Frederick Ausubel, Jon Beckwith and Karen Janssen, "The Politics of Genetic Engineering: Who Decides Who's Defective?" *Psychology Today*, June, 1974; Paul Ramsey, "On In Vitro Fertilization," (Chicago: Americans United for Life, 1979); Lord Ritchie-Calder, "The Tailor Retailored," *1976 Britannica Book of the Year*, Special Supplement; Joseph Fletcher, *The Ethics of Genetic Control* (Garden City, NY: Anchor Books, 1974); Joshua Lederberg, "Experimental Genetics and Human Evolution," *The Bulletin of the Atomic Scientists*, October, 1966; Leon Kass, "New Beginnings of Life," in Michael Hamilton,

Today, molecular biologists probe and analyze the basic chemical substances of living matter. Human genes are being mapped, photographed, analyzed, transplanted, synthesized. Geneticists gaze into the very mysteries of life, searching for the keys that will one day unlock the doors to the biological control of the future of humanity. Many such keys have already been found. To Harvard Nobel laureate, Salvador Luria, "the relevant point . . . is that all essential features of the genetic process, insofar as they have been clarified, have turned out to be interpretable in strictly biochemical terms. What molecular biologists have done is to make the genetic mechanism directly available to chemical experimentation."²⁶

Dr. James F. Crow, former chairman of the biology department of the University of Wisconsin, says that "it is clear that biological and chemical possibilities for influencing human evolution and development are certain to come, probably before we have thought them through."²⁷ A report issued by the Subcommittee on Science, Research and Development of the House of Representatives is even more explicit: "The science of genetics is rapidly mov-

ed., *The New Genetics and the Future of Man* (Grand Rapids, Mich: Eerdmans); James D. Watson, "The Future of Asexual Reproduction," *Intellectual Digest*, Vol. 2, no. 2, 1971; Kenneth Guentert, "Will Your Grandchild Be a Test Tube Baby?" *U.S. Catholic*, June, 1977; James F. Danielli, "Artificial Synthesis of New Life Forms," *The Bulletin of the Atomic Scientists*, December, 1972; Marc Lappé, "Moral Obligations and the Fallacies of Genetic Control," *Theological Studies*, vol. 33, no. 3 (September, 1972); Caryl Rivers, "Genetic Engineering: Now That They've Gone Too Far, Can They Stop?" *Ms.*, June, 1976; Donald Huisinigh, "Should Man Control His Genetic Future?" *Zygon*, 42 (February, 1969); Robert Sinshemer, "The Dawn of Genetic Engineering," address to the Genetics Society of America (August, 1975).

²⁶Salvador Luria, "Modern Biology: A Terrifying Power," *The Nation*, October 20, 1969.

²⁷Quoted in *Bioscience*, December, 1966.

ing out of the realm of theoretical research and into the more politically sensitive region of applied science. The technological capability to alter the course of human evolution is relatively close at hand."²⁸

In the last analysis, recombinant DNA and other genetic engineering techniques will not be confined to mere microorganisms. Significant breakthroughs are now being made that will lead to human genetic engineering. In October of 1979, Dr. W. French Anderson of the National Heart, Lung and Blood Institute, announced that his team of researchers had achieved a major breakthrough by successfully injecting a single gene into a defective living cell, "curing" that cell's genetic flaw. Anderson's success is an important step toward the day when human genetic manipulation will be possible.²⁹

In human terms, the Journal of the American Medical Association defines genetic engineering as follows:

"The popular term, genetic engineering, might be considered as covering anything having to do

²⁸*Genetic Engineering: Evolution of a Technological Issue*, Report to the Subcommittee on Science, Research and Development of the Committee on Science and Astronautics, House of Representatives, November, 1972.

²⁹Harold Schmeck, "Injection of a Gene Cures Flaw in Cell," *The New York Times*, October 10, 1979. Other relevant articles on recent important breakthroughs in genetic research include: Mary Jane Schier, "Gene Research: Unique Achievement Reported Here," *Houston Post*, October 17, 1979; "Doctors Isolate Single Gene; Step in Birth Defects Study," *The Washington Post*, July 28, 1978; Jack D. Griffith, "DNA Structure: Evidence from Electron Microscopy," *Science*, vol. 201 (11 August 1978); "Gene Injection Remedies Cell Defect," *Science News*, vol. 116.

with the manipulation of the gametes or the fetuses, for whatever purpose, from conception other than by sexual union, to treatment of disease in utero, to the ultimate manufacture of a human being to exact specification . . . Thus, the earliest procedure in genetic engineering . . . is artificial insemination, next . . . artificial fertilization . . . next artificial implantation . . . and finally, what is popularly meant by genetic engineering, the production — or better the biological manufacture — of a human being to desired specifications."³⁰

Significantly, with the exception of the full-scale manufacture of human beings to desired specifications, all of the processes outlined by JAMA have already been accomplished with human beings.

As we embark upon this course of the technological alteration of the human germplasm, and the germplasm of other mammals such as cattle, significant moral and ethical issues are raised. Some observers worry that the very technology that ushers in the Genetic Age will inevitably violate the human spirit. Ethicist and author Dr. Leon Kass, himself a molecular biologist trained at Harvard, argues that "increasing control over the product is purchased by the increasing depersonalization of the process."³¹ Jacques Ellul, the French philosopher and social critic, predicts that we will eventually become overwhelmed and consumed by the biological technology we create: "When technique enters into every area of life, including the human, it ceases to be external to man and becomes his very substance. It is no

³⁰"Genetic Engineering: Reprise," *Journal of the American Medical Association*, vol. 220, no. 10 (June 5, 1972).

³¹Leon Kass, "Making Babies — The New Biology and the 'Old' Morality," *The Public Interest*, Winter, 1972.

longer face to face with man, but is integrated with him, and it progressively absorbs him."³² Pursuing Ellul's line of thought, Dr. Salvador Luria asks, "When does a 'repaired' or 'manufactured' man stop being a man . . . and become a robot, an object, an industrial product?"³³

Dr. Luria's comments are highly relevant to the case at hand, for one day it *will* be possible to convert higher organisms, including human beings, into "industrial products" just as microorganisms are being so engineered today. A ruling in 1980 favoring patents on living organisms will open the way to patents of higher forms of life in the years to come.

The majority in the lower court has naturally contended that such is not the case. Judge Rich (October 6, 1977) has written in his Bergy ruling: "As for the . . . fears that our holding will of necessity, or 'logically,' make all new, useful and unobvious species of plants, animals and insects created by man patentable, we think the fear is far-fetched." Elsewhere in the opinion, the majority ruled that the Bergy and Chakrabarty microorganisms are "much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees, or raspberries and roses."³⁴

PBC believes that the majority was short-sighted and relied upon dubious logic in arriving at these conclusions. As Judge Miller correctly noted in his dissent to the majority opinion:

Such a distinction is purely gratuitous and clearly erroneous. The nature of organisms, whether

³²Jacques Ellul, *The Technological Society* (New York: Vintage, 1974).

³³Luria, *ibid.*

³⁴563 F.2d 1031. As reported in Solicitor General's Petition for Writ of Cert. to Supreme Court, p.124a.

microorganisms, plants or other living things, is fundamentally different from that of inanimate chemical compositions. For example, both the microorganisms claimed herein and honeybees are alive, reproduce, and act upon other materials to form technologically useful products (lincomycin and honey, respectively). This cannot be said of chemical compositions.³⁵

The thing which sets living organisms apart from nonliving entities is their very "aliveness." If this basic fact is not accepted, then there is no place to draw the line concerning which living things are patentable and which are not. Either all forms of life altered through genetic engineering are patentable subject matter under 35 U.S.C. 101, or none are. The logic of patenting life holds that altered living organisms which perform functions similar to nonliving-chemical compositions are patentable. If this view is adopted, there is then no viable distinction between lower and higher organisms. After all, a horse (a living organism), can perform a function similar to a tractor (a man-made composition of matter): both can pull a plow. Should then genetically altered or asexually reproduced horses be subject to patenting? If patents are awarded on microorganisms, the answer must be 'yes.'

Ironically, the impossibility of differentiating between genetically altered lower and higher life forms is best articulated in *amicii* presented the lower court by the Regents of the University of California and Genentech, both of which support life form patents.

Noting that recent research with viruses has led some scientists to ponder whether these organisms are actually to be classified as dead or alive — as living beings or as chemical material — the University quotes one scientist as saying,

³⁵*Id.*

"The gap between life and nonlife has disappeared." The University goes on to assert:

Recognition of the difficulty that skilled scientists are experiencing in drawing a bright line between life and its absence effectively destroys the argument that life itself is not only *the essential characteristic* of *any* living being — even a microorganism — but *the one* which, so long as unaltered precludes patentability. Surely where the line between life and nonlife is so fine as to baffle even the experts in the art and at times cannot be drawn with conviction, compositions of matter or manufactures near the periphery cannot conveniently be deemed patentable or unpatentable on so ephemeral a ground."³⁶

A microorganism, the University argues, is so close to "the periphery" of life that there should be no obstacle to patenting it, and indeed to proclaiming it non-living. A microorganism may be a thing of small consequence to most people. But where and how will we draw the line once we embark on a course of classifying life at "the periphery" as so inconsequential that it is patentable material? Perhaps Genentech, in its own amicus brief supporting patents for life forms, has provided an answer. The company notes that more than a century ago, Claude Bernard observed:

"(A) created organism is a machine which necessarily works by virtue of the physico-chemical properties of its constituent elements. Today we differentiate three kinds of properties exhibited in the phenomena of living beings: physical properties, chemical properties, and vital properties. But the term 'vital properties' is itself only provisional; because we call properties vital

³⁶In brief amicus curiae of the University of California, Berkeley, in the matter of the application of Malcolm E. Bergy, et al., pp. 15-16.

which we have not yet been able to reduce to physio-chemical terms; but in that we shall doubtless succeed some day."³⁷

Here we confront the essence of the matter which is inherent in the case now before the Court. To justify patenting living organisms, those who seek such patents must argue that life has no "vital" or sacred property; that all of life's properties can ultimately be reduced to the "physico-chemical." But once this is accomplished, all living material will be reduced to an arrangement of chemicals, or mere "compositions of matter." When this happens, all life will move toward that "periphery" in which the University of California claims life does not have to be treated as life at all.

This is the modern scientific view of man and woman. Reproduction is analyzed in terms of the interaction of chemical units contained in the sperm and egg; the brain is mapped and manipulated with electronic and chemical stimulants to "explain" how thought processes work; sociobiologists reduce human emotions like love and altruism to an ill-defined genetic base.

The case before the court may not appear to involve the life and death issues and passions of abortion, euthanasia or brain death rulings. Nonetheless, appearances aside, this case actually eclipses the import of these others because, in reaching a decision, a precedent-setting determination of the very nature of life will have to be decided upon. Whether such a definition is explicitly stated by the Court or not, hardly matters. If a ruling in favor of patenting genetically engineered living organisms is forthcoming,

³⁷In brief amicus curiae of Genentech, in the matter of the application of Ananda M. Chakrabarty, p. 8.

then manufactured life — high and low — will have been categorized as less than life, as nothing but common chemicals.

It is no exaggeration to state that those who favor the granting of patents in this case would welcome just such a definition of manufactured life being of less value than naturally occurring life. The American Patent Law Association brief in support of patents, argued below:

The distinguishing characteristic of a product of nature is not "life" but its existence without the intervention or industry of man and the distinguishing characteristic of a manufacture is not its 'non-life' but its existence through industry of man. The bar to patentability for natural products involves not life but lack of novelty.

"History has shown that the interjection of differentiations based on a mystical 'life' component are seldom scientifically valid."³⁸

This is the internal logic that comes to be adopted once *any* forms of living organisms are deemed patentable. If this Court rules in favor of life form patents, it will serve to institutionalize this reductionist and cold philosophy. Further, a ruling in favor of GE and Upjohn will actually dramatically accelerate the very technological developments which will one day make human genetic engineering a reality.

Dr. Leon Kass provides eloquent testimony to the enormity of what is at stake:

We have paid some high prices for the technological conquest of nature, but none

³⁸In brief amicus curiae of the American Patent Law Association, in the matter of the application of Bergy, et al., pp. 4 and 5.

perhaps so high as the intellectual and spiritual costs of seeing nature as mere material for our manipulation, exploitation and transformation. With the powers for biological engineering now gathering, there will be splendid new opportunities for a similar degradation of our view of man. Indeed, we are already witnessing the erosion of our idea of man as something splendid or divine, as a creature with freedom and dignity. And clearly, if we come to see ourselves as meat, then meat we shall become. The new technologies for human engineering may well be "the transition to a wholly new path of evolution." They may, therefore, mark the end of *human* life as we and all other humans know it. It is possible that the non-human life that may take our place will in some sense be superior — though I personally think it most unlikely, and certainly not demonstrable. In either case, we are ourselves human beings; therefore, it is proper for us to have a proprietary interest in our survival, and in our survival as human beings. This is a difficult enough task without having to confront the prospect of a utopian, constant remaking of our biological nature with all-powerful means but with no end in view.³⁹

³⁹Kass, *ibid.*

CONCLUSION

For the foregoing reasons, the judgment of the court below should be reversed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 13, 1979, I deposited in the United States mail, postage prepaid, three copies of the attached brief Amicus Curiae, addressed to each of the counsel for the Parties listed below:

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IN THE

Supreme Court of the United States

October Term, 1979

No. 79-136

LUTRELLE F. PARKER, Acting Commissioner of
Patents and Trademarks,

Petitioner,

vs.

MALCOLM E. BERGY ET AL and
ANANDA M. CHAKRABARTY,

Respondents.

**On Writ of Certiorari to the United States Court of
Customs and Patent Appeals**

**MOTION FOR LEAVE TO FILE BRIEF AMICUS
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December 12, 1979

IN THE
Supreme Court of the United States
October Term, 1979

No. 79-136

LUTRELLE F. PARKER, Acting Commissioner of
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Respondents.

**On Writ of Certiorari to the United States Court of
Customs and Patent Appeals**

**Motion on Behalf of Cornell D. Cornish and the
Village of Belle Terre as Amicus Curiae**

This motion is made by Cornell D. Cornish on behalf of himself and the Village of Belle Terre to file this brief as Amicus Curiae in the subject case out of time and by waiving the required consent of the parties in writing. So far the consents of the attorney for Bergy et al and the Solicitor General have been received. The attorney for Chakrabarty has not given his consent.

Respectfully submitted,

CORNELL D. CORNISH
as Amicus Curiae

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IN THE
Supreme Court of the United States
October Term, 1979

No. 79-136

LUTRELLE F. PARKER, Acting Commissioner of
Patents and Trademarks,
Petitioner,
vs.

MALCOLM E. BERGY ET AL and ANANDA M. CHAKRABARTY,
Respondents.

**On Writ of Certiorari to the United States Court of
Customs and Patent Appeals**

**BRIEF OF CORNELL D. CORNISH
AS AMICUS CURIAE**

Interest of Amicus Curiae

As a patent attorney, Cornell D. Cornish has a federal right of clear statement to represent inventors of new, useful, unobvious, enablingly disclosed and particularly claimed microorganisms not barred by law before the U.S. Patent and Trademark Office. The right is preemptive. *Sperry v. State of Florida*, 137 USPQ 578 (1963).

As an inventor, he has a property right to emancipation by practicing his profession free from uncontrolled regulations, prior restraint, and content regulation. To this end he has a common law right of publicity to first disclose and to dedicate his microorganisms to the public in a patent unless barred by law. Publicity is such a right. *Zacchini v. Scripps-Howard Broadcasting Co.*, 443 U.S. 562, 577 and n. 13. Neither the patent statutes nor the Constitution supports the doctrine of election of recognition under 35 USC 101, 171, or 161, etc. *In re Yardly*, 493 F. 2d 1389, 181 USPQ 331 (CCPA 1974); *Patents*, Donald Chisum, Sec. 1.04 (5), 1979, p. 1-157. The patent laws overlap in terms of subject matter, just as the patent and copyright laws do. 1 Nimmer, *Copyrights*, Sec. 38 (1975). Obviously this overlap is not complete. *Mazer v. Stein*, 347 U.S. 201; 100 USPQ 325 (1954). That is the reason for having more than one statute. The requirements are different. So are their terms. The clear statement of the law is to provide for dual coverage in appropriate cases, and different coverages simultaneously, save only if the term is increased. *Korzybski v. Underwood & Underwood, Inc.*, 36 F. 2d 727, 3 USPQ 242 (2d Cir. 1929). These are property rights of clear statement whether the subject matter be *parasexually* created, *synergistically* regenerated, *asexually* made and/or *sexually* reproduced.

As an inventor he also has a common law and Constitutional right of clear statement to be free of prior restraint and/or content regulation of his thought and inquiry. *Edwards Case*, Mich. 6 Jacobil, 77 Eng. Rep. 1421 (KB 1609). An attempt was made to limit this doctrine of "no prior restraint" in the *Patent Act of 1790*. It made a patent a matter of grace. However, this Government attempt to deny a patent, e.g., because of subject matter, was eliminated when the *First Amendment* was adopted in 1791. This is supported by the maxim *leges posteriores priores contrarias abrogant*. 1 Bl. Comm. 59-62 (8th ed. 1778). Thus, the subject matter of patents was allowed to develop as a property right and to expand unhindered by federal legislation. *In re Seaborg*, 140 USPQ 662 (CCPA 1964). *The Patent Act of 1793* adopted this policy of clear statement.

As an inventor he also has a statutory right under 35 USC 101 to disseminate and to dedicate his invention to the public in a patent unless barred by law. 42 USC 2181 is a statute that limits the subject matter of a patent. It is essential to me as an inventor that 35 USC 101 be interpreted in such a way that it will not violate established policies of clear statement. This Court has been careful not to limit the ways in which the *First Amendment* can be abridged. *Grossjean v. American Press Company, Inc.*, 297 U.S. 233; *Sai v. The State of New York*, 334 U.S. 558. These are rights of clear statement.

This Court has often expressed concern about the confusion and the retroactivity problems that inevitably would result with a judicial overturning of long lines of precedents. *Federal Baseball Club of Baltimore v. National*

League of Professional Baseball Clubs, 259 U.S. 200 (1922); *Toolson v. New York Yankees, Inc.*, 346 U.S. 63; *Flood v. Kuhn*, 407 U.S. 259. See also *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976); and *Parker v. Flook*, 437 U.S. 584, 595, footnote 18; 198 USPQ 193 (1978). See also U.S. Patents 3,832,801 and 3,683,550 on man made plants. These plants are *parasexually* created subject matter under 35 USC 101. According to *The Wall Street Journal*, Aug. 18, 1972, the former invention was limited to a single specific "fused cell". The confusion would extend to International Law since living organisms are patentable in foreign countries. See British Patent 1,310,119. Under the *Paris Convention* of 1883 and the *PCT Convention* of 1978 applicants should be allowed to file first here and then in convention countries on living organisms. These are obviously well established policies of clear statement to cover subject matter that is *parasexually* created.

As an inventor, he also has a right in not surrendering microorganisms to the States. The surrender of living organisms from 35 USC 101 would be in derogation of his rights as an inventor. To this end, it would violate established policies of clear statement involving preemption of patents by the Federal Government. *Sperry v. State of Florida*, 137 USPQ 578 (1963). For the *Tenth Amendment* states the obvious. What is not surrendered is retained. *United States v. Darby*, 312 U.S. 100, 124. And what is given up is possessed by the States. *Gibson v. Ogden*, 9 Wheat. 1, 14, 46, 47, 59 (1824); *Livingston v. Van Ingen*, 9 Johns (NY) 507 (1812); *McLain v. Ortmyer*, 141 U.S. 76, 78 4/9 (1891). It is thus essential that the legislative enactment of 35 USC 101 be interpreted so as not to violate this established policy of clear statement. It is consistent with the

plain meaning of the statute. To this end, it is the rule of statutory construction that this legislative enactment be given its intended general, comprehensive and prospective interpretation by applying it alike and with global equality to *all* persons and *any* subject matters within its general purview and scope coming into existence subsequent to its passage. *Commonwealth v. Maxwell*, 271 Pa. 378, 114 Atl. 825 (1921); 25 Ruling Case Law 778.

Moreover, this intended prospective interpretation must be provided so as not to violate the established competitive mandate of the Constitution. This is also a clear policy statement. To this end, the patent system must be open to all with global equality, whether the subject matter be old or new technology, living or dead. Analogues abound. One such analogue is the post office. Also, common carriers are much the same in their prospective duties to new technologies. At common law a carrier owes a duty to the public whatever the subject matter that comes into existence to carry for all to the extent of its capacity, at reasonable rates, and with substantial impartiality. *Michigan Public Utilities Commission v. Duke*, 266 570 U.S. 370. For it has long been pointed out that an unrestrained right of discretion would, through its operation upon the course of trade, tend to build up monopolies and destroy competition. 9 Am. Ju. 557, 1937, citing *Messenger v. Pennsylvania R.R. Co.*, 37 NJL 531; 18 Am. Rep. 754.

These well established common law, constitutional and statutory policies of clear statement are consistent with the plain meaning of 35 USC 101, as well as its legislative history. The flow of action was dominated by the Examiner-in-Chief of the Patent Office. He testified that the prospec-

tive subject matter intended under 35 USC 101, "may include anything under the sun that is made by man." On the other hand, the lonely view of T. Hayward Brown, which was not adopted, was that 35 USC 101 shouldn't open the door to new technology, including new "discoveries in the fields of chemistry, physics, medicine, mathematics, et cetera." This is precisely where the subject inventions and those of Cornell D. Cornish are to be found. See U.S. 3,433,705 and *Hearings*, 82nd Congress, First Session, H.R. 3760, June 13-15, 1951. To give 35 USC 101 anything other than the broadest meaning the plain meaning of the words will bear would obviously violate established policies of clear statement. The plain meaning of the words was to advance the progress of new species, not to suppress or endanger them. The flag of Galileo was clearly intended to be flown then and not to be torn down now. The well established policy of clear statement was to secure and recognize the prospective dissemination and the dedication of inventions to the public in patents coming into existence after the enactment of the patent law. *Korzybski v. Underwood & Underwood, Inc.*, 36 F. 2d 727, 3 USPQ 242 (2d Cir. 1929). And 35 USC 101 was a codification of this law. *Hearings*, 82nd Congress, June 13-15, 1951.

The plain meaning of 35 USC 101 is clearly consistent with prospective subject matter coming into existence subsequent to its passage. To this end, the plain meaning of "any" is *any* invention under the sun really made by humans. On the other hand, the word "any" in 35 USC 101 is clearly limited to "Whoever" invents or discovers a reality based upon sensory perception. By the maxims of statutory interpretation, this means "man made" inven-

tions and discoveries, and those *synergistic* inventions that are regenerated by the cooperation of divine grace and human activity. *In re Sarkar*, 200 USPQ 132 (CCPA 1978); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 61 (1969); *Sakraida v. Ag-Pro, Inc.*, 425 U.S. 273, 282 (1976); and *Webster's New Collegiate Dictionary*, "synergism", 1953. Thus, they exclude inventions that are not embodied, that are merely ideas, etc. *Parker v. Flook*, 437 U.S. 584. See the maxims: *expressio unius exclusio alterius*, *noscitur a sociis*, *eiusdem generis*, and *reddendo singula singulis*. "Statutes And Their Interpretation," Dean Albert M. Sacks, Program of Instruction For Lawyers, Harvard University, July 18-21, 1979, p. 1412. If this Court finds that the subject inventions were really made by humans, and are not merely ideas, then Cornell D. Cornish, as well as all other inventors, rich and poor, black and white, young and old, well fed and hungry, domestic and foreign, male and female, and those unable to publish elsewhere, who wish to be emancipated, may seek the same with global equality by recognition in a patent not barred by law. It is our right to keep the delegation to the Patent and Trademark Office clearly in view. *A.L.A. Schechter Poultry Corporation v. United States*, 295 U.S. 495 (1935). It is one of the largest printing houses of technical information in the world. This information is largely available from no other source. Thus, if new reasons are adopted for stopping applicants from going before the Patent and Trademark Office, they should be articulatable reasons. There is a clear analogy here to the criminal law. *Delaware v. Prouse*, 99 S. Ct. 1391 (1979).

Cornell D. Cornish has an interest in this case for the reasons stated in the above-identified motion to permit filing of the attached brief. His interests as a patent attorney and an inventor are believed to be compelling. Indeed, the connection between this case and his interests under the *First Amendment* are clearly before this Court because of the citations in the Solicitor General's Petition for Writ of Certiorari to the United States Court of Customs and Patent Appeals, dated July 1979, in this case. See, e.g., *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-381 (1969), cited on the last page of the Petition. See also this Court's view of the unified, general, comprehensive and prospectively operative communications policy of the United States relative to its clear statement in patent and common law policy. *Zacchini v. Scripps-Howard Broadcasting Co.*, 97 S. Ct. 2849 (28 June 1977). Moreover, the connections between these cases and the *First Amendment* have been extensively discussed in the literature. *Taming Red Lion: The First Amendment and Structural Approaches to Media Regulation*, Federal Communications Law Journal, Vol. 31, No. 2, Spring 1979, pp. 215-234; *Cable Television and Content Regulation: The FCC, The First Amendment and The Electronic Newspaper*, New York University Law Review, Vol. 51, No. 1, April 1976, pp. 133, 144; *Human Cannonballs and the First Amendment: Zacchini v. Scripps-Howard Broadcasting Co.*, Stanford Law Review, Vol. 30, No. 6, July 1978, pp. 1185-1209. Cornell D. Cornish is also a resident of Belle Terre, Port Jefferson, New York.

Belle Terre is a quiet, residential community. *Belle Terre v. Boras*, 41 S. Ct. 1536 (1974). It owns land touching

Port Jefferson Harbor. This harbor serves as a main port of entry for oil into Suffolk County. Thousands of tons of oil are involved on an almost daily basis. Oil spillages have been of concern here also to the Federal Government. See the following. The Chakrabarty invention would be especially helpful to us in protecting Belle Terre against oil spills. We thus have a direct property interest in the allowed claims. Their dedication to us will result from a patent thereon.

Belle Terre is a village on Long Island. It has a property interest in publicly owned, oil-free beaches and fishing grounds, not only at Port Jefferson. The residents of Belle Terre have a property interest in oil-free beaches and fishing grounds in the whole of Suffolk County. The Chakrabarty invention would be a property interest to the residents of Belle Terre in protecting Long Island's shores and adjacent fishing grounds from oil spills at George's Bank. According to the *New York Times*, October 12, 1979, Americans landed fish worth \$82 million from the Bank. Foreigners took another \$85 million. Over the next 20 years the total catch might be worth \$3.3 billion. Government geologists estimate the most probable yield from the lease area involved to be 123 million barrels of oil and 870 billion cubic feet of gas, worth \$7 billion over the 20-year life of the field. A patent on the allowed claims is thus a valuable property even after 17 years.

According to the *New York Times*, October 31, 1979, there have been law suits to stop the sale of oil and gas leases at George's Bank. Also at stake is the continued viability of the George's Bank, which for almost 300 years has been one of the world's richest fishing grounds. Its tourist

industry last year netted Massachusetts alone \$1.7 billion. Obviously, the Chakrabarty invention could be of interest to New England as well. The acceptance of the allowed claims in a patent would thus be a valuable property asset to us which we could use for many important purposes.

According to the *New York Times*, November 10, 1979, 84 percent of the households on Long Island are heated by oil. The Port Jefferson plant of the Long Island Lighting Company is currently run by oil that comes in by tanker through Port Jefferson Harbor. It is substantially the only source of electricity for all the residents of Belle Terre. Thus, the acceptance of the allowed claims is a vital property to us. It would dedicate a vital property interest to us.

According to the *New York Times*, November 6, 1979, the Government has petitioned this Court in the case of *United States v. Ward*, No. 79-384. In 1978, the Government's petition said, 14,741 oil spills were brought to the Coast Guard's attention. These resulted in 8,000 civil penalty cases, including 1,400 against individuals. Moreover, these oil spills are important to the Environmental Protection Agency, regulations governing the discharge of hazardous substances, other than oil, into Federal waterways, and the Clean Water Act. According to 33 USC the oil spills prohibited means oil of any kind or in any form, including fuel oil, sludge, and oil refuse. See e.g., 33 USC 407, 411, 413, 432, and 433. It is obvious, therefore, why we have a property interest in accepting the allowed claims.

Additionally, Cornell D. Cornish has a property interest in a covenant running with land on Port Jefferson Harbor. This covenant, which is still in effect, is recited in the deed

of the land recorded in Suffolk County, N.Y., in *Liber 1033 cp 578*, for land transferred from Belle Terre Park Co., Inc. to the Harbor Head Corporation. This covenant is certified in writing by the Home Title Division, Chicago Title Insurance Company. It provides that no nuisance shall be maintained on said property. In connection with this land a request by Mr. Samuel S. Giles for a Department of the Army permit for Application No. 74-139 to construct a marina at Mt. Misery Point, Town of Brookhaven, Port Jefferson Harbor was denied. This denial was dated 2 August 1977 in accordance with Title 33 CFR 325.8 (b), Processing of Department of the Army permits (as published in the *Federal Register* on Tuesday, 19 July 1977; Vol. 42-No. 138). According to this denial by John J. Chisholm, LTC, Corps of Engineers, the vicinity of this land "is of high biological importance." It involves "shallow water habitat in Port Jefferson Harbor of value to fish and wildlife resources." Obviously, therefore, Cornell D. Cornish for himself and the Village of Belle Terre has an interest in the specific microorganism for cleaning up oil spills that was invented by the applicant Chakrabarty in this case. We specifically have a direct and immediate property interest in the dedication of the allowed claims.

As referred to in the below mentioned report, a map of Port Jefferson Harbor, Belle Terre, Port Jefferson and Long Island is attached to the report entitled, *Port Jefferson Harbor, New York, Review of Reports*, which was published by the U.S. Army Engineer District, New York, August 1964, Revised July 1966. The proximity of Long Island to George's Bank is also shown by this map. The many places we could use the property from the dedication of the allowed claims is obvious from the map.

As mentioned in the above-identified *Review of Reports*, the projected trend of petroleum commerce in Port Jefferson Harbor is based on three factors: population increase, diversion to Port Jefferson Harbor of a portion of the petroleum traffic of neighboring shallow-draft ports in Suffolk County, and continued use of oil by the Long Island Lighting Company power plant. The population of Suffolk County, which comprises the tributary area of Port Jefferson Harbor, has been increasing at an accelerated rate, greater than the national average. The population was about 1,000,000 in the 1970's. It is expected to increase to about 3,000,000 in 2020. In 1970 the domestic petroleum commerce in Port Jefferson Harbor was estimated to be about 1,010,000 tons, and the foreign commerce to be about 450,000 tons. In 2020 the total petroleum commerce is projected to be about 3,000,000 tons. That is estimated to be worth about \$1 billion/year. This is in addition to the value of the dedication of the allowed claims to us in a patent.

There is one 100-acre County Park on Port Jefferson Harbor. There are numerous Belle Terre Village parks on Port Jefferson Harbor to which Cornell D. Cornish and all the residents of Belle Terre have a property interest by dedication. It would be a property interest to us in the use of these parks to have Chakrabarty disclose his invention to the public in a patent in an oil eating composition of matter, manufacture, material, art, and improvements thereof. Moreover, it would be a direct and valuable property interest to us to have Chakrabarty dedicate his invention and improvements to the public, save for the limited exclusive rights therein mandated by Congress. These inventions are public goods, like national defense, which would

be subject to free-riders except for the system of Government mandated by the Constitution. Possibly they wouldn't exist at all without the open and personal disclosures in patents. New technology was the result beginning from the adoption of the *Bill of Rights* and/or before. It is in a direct line from the letters patent used to implement the Magna Carta. *The Magna Carta and the Tradition of Liberty*, L. B. Wright, 1976, p. 58. They are directly related to the patents used for dedication by Galileo. All those inventors who were recognized and/or emancipated after Galileo according to the clear statements of the Constitution and the clear intention of Congress used patents for dedication. This dedication of property was clearly intended under 35 USC 101 and the patent laws going back to the *Patent Act of 1793*. Our property interest in accepting the allowed claims for dedication to the public is clear, direct, immediate and valuable. We shouldn't be deprived of this valuable property, nor should it be surrendered except by statute. And such a statute must be explicit. It should not be implied by this Court. *U.S. Constitution, Art. IV, sec. 3, cl. 2*; 5 USC 553 (A.P.A.); and *Public Citizen, Inc. v. Sampson*, 180 USPQ 497 (DC, DC 1974).

The Constitutional Provisions, Statutes and Regulations Involved

For convenience, the relevant constitutional, statutory and regulatory provisions are set forth in the Appendix, which appears at the conclusion of this brief.

Summary of Argument

The Patent and Trademark Office must have wide discretion in rejecting the claims of the applicants without prejudice to their refiling of the rejected claims in Continuing or Reissue Applications.

ARGUMENT

I.

The Patent and Trademark Office must have wide discretion in mediating the issuance of patents in such a way as to free it from not insubstantial constitutional doubts.

The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious. *Parker v. Flook*, 437 U.S. 584 (1978). As part of the mediating process the Patent and Trademark Office has been able to determine what type of discovery is sought to be patented, i.e., one that is not banned by law from disclosure in a patent. Moreover, since claims have been allowed, the Patent and Trademark Office has been able to determine that the disclosures are entitled to issuance in patents without content regulation, i.e., that the claimed inventions are not only new and unobvious, but that they are also useful, enablingly disclosed and particularly claimed.

Claims have also been rejected under *35 USC 101*. This is part of the mediating process. But a statute should be interpreted, if fairly possible, in such a way as to free it

from not insubstantial constitutional doubts. *Lynch v. Overholser*, 369 U.S. 705, 710 (1962). Thus, the Patent and Trademark Office must have wide discretion in mediating the issuance of patents in such a way as to free it from not insubstantial constitutional doubts.

II.

In view of the allowance of claims, the rejection of other claims should be upheld without prejudice to the applicants' filing of continuing and/or reissue applications as part of the mediating process.

As part of the mediating process the Patent and Trademark Office has wide discretion in mediating the issuance of continuing and reissue patent applications as patents. *Grant v. Raymond*, 31 U.S. (6 Pet.) 218 (1832); *O'Reilly v. Morse*, 56 U.S. (4 How) 62, 112 (1853). To this end, it can even reject claims while permitting the applicants to file continuing and/or reissue patent applications on the rejected claims. At this time the applicant may choose to abandon the claims that were rejected as part of the mediation process. On the other hand, the applicant can choose to file a continuing application and a reissue application. The latter has the advantage of publication before reissuance as a patent. This has the advantage of gaining the consent of the public to the reissuance of the patent. On the other hand, the public can sometimes show that the reissuance of the patent is banned by law. If this Court agrees, therefore, in view of the allowance of claims, and the issues not briefed, the rejection of the rejected claims should be upheld without prejudice to the applicants' filing of a continuing and a reissue application as part of

the mediating process. This would free 35 USC 101 from not insubstantial constitutional doubts that might otherwise arise. It would also put applicants on notice of the Patent and Trademark Office's intention to enforce the decision of the Court. The FTC does something similar. 16 CFR Sec. 1.1-1.4.

The Guidelines relating to the reissue statute 37 CFR 1.175 and 1.291, as amended effective March 1, 1977, are found in the December 12, 1978 *Official Gazette*, 977 OG 11. The *Rules of Practice In Patent Cases* relating to Reissues are found in the February 22, 1977 *Official Gazette*. On October 4, 1976, notice was given in the *Federal Register* (41 FR 43729) of the rules, which are found in Title 37 of the *Code of Federal Regulations* relating to Reissue Applications. The filing of protests under 37 CFR 1.291, is discussed in 977 OG 12 *et seq.* Relevant sections of the *Manual of Patent Examining Procedure*, comprise Sections 1309.02 and 721.01. The thrust of all these rules and regulations is to have the public help the Patent and Trademark Office avoid issuing patents that are barred by statute. Indeed, the problem of workload was seriously addressed in *Parker v. Flook*. Moreover, Federal Judges can direct patentees to seek reissue. 451 PTCJ A-14, October 25, 1979. Inventorship is one of the questions addressed in such instances, i.e., whether this invention was made by "man" or not.

Conclusion

This Court should uphold the rejection of claims as part of the mediating process in issuing patents without prejudice to the applicants to file continuing and/or reissue applications on the rejected claims.

Respectfully submitted,

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December 12, 1979

APPENDIX

United States Constitution and Statutes

The Constitutional Provisions

U.S. Constitution, Article IV, Section 3, clause 2 provides in pertinent part: "The Congress shall have Power to dispose of and make all needful Rules and Regulations respecting the territory or other property belonging to the United States."

First Amendment. Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof, or abridging the freedom of speech, or the press; or the right of the people peaceably to assemble, and to petition the Government for the redress of grievances.

Tenth Amendment. The powers not delegated to the United States by the Constitution nor prohibited by it to the States, are reserved to the States respectively, or to the people.

United States Code

Title 35 — Patents

Patent Act of July 19, 1952,

C. 950, Sec. 1, 66 Stat. 792

Section 101, Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

IN THE
Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-136

SIDNEY A. DIAMOND, Commissioner of
Patents and Trademarks, *Petitioner*

v.

ANANDA M. CHAKRABARTY

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEAL

BRIEF OF:

Dr. Leroy E. Hood, Dr. Thomas P. Maniatis, Dr. David S. Eisenberg,
The American Society Of Biological Chemists, The Association Of
American Medical Colleges, The California Institute of Technology,
The American Council On Education As *AMICI CURIAE*.

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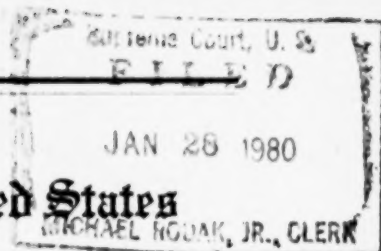
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INTEREST OF AMICI CURIAE

Amici Curiae are biochemists and molecular biologists working in university laboratories, a learned society devoted to the extension of biochemical knowledge, a university pre-eminent in scientific research, and associations of medical schools, post-secondary schools and learned societies whose members are engaged in biomedical research and delivery of health care.¹

Each of the individual Amici Curiae is engaged in research involving molecular biology. Dr. Maniatis, at the California Institute of Technology, is generally acknowledged to be one of the leaders in the field of recombinant DNA technology.² He, together with Dr. Hood, who is also at the California Institute of Technology, is using recombinant DNA techniques to produce interferon, an antiviral drug, from bacteria. Dr. Eisenberg studies the atomic structure of biological molecules. The research conducted by Amici has immediate applications in the fields of immunology and pharmacology, and long range significance for many areas of agriculture and medicine.

The American Society of Biological Chemists is a nonprofit corporation, organized under the laws of the State of New York and devoted to the extension and utilization of biochemical knowledge. The Society's 5,000 members are elected on the basis of their scientific qualifications and excellence in the fields of biochemistry and molecular biology. Members of the Society are employed by universities, research foundations, government laboratories and commercial corporations.

¹ The parties in this case have granted approval to these Amici to file this Brief. Their letters of approval have previously been filed with the Court.

² Recombinant DNA involves the transfer of genetic material from one organism to another thereby "constructing" new strains of bacteria. The extraordinary promise of this technology has led scientists to compare it in importance to the discovery of nuclear fission and fusion. *Recombinant DNA: Accelerated Processing of Patent Applications For Inventions*, 42 Fed. Reg. 2712 (1977).

Another of the Amici, the Association of American Medical Colleges, is a voluntary, non-profit corporation established under the laws of the State of Illinois, having its principal place of business in the District of Columbia. Its corporate purpose is the advancement of medical education. Its institutional membership includes virtually all (125) accredited and operating non-profit medical schools in the United States. Membership also includes over 400 teaching hospitals in which undergraduate and graduate medical education is conducted, and 68 academic and professional societies, the members of which are actively engaged in medical education and biomedical research. Together, the members of the Association and the medical colleges conduct a substantial portion of the nation's biomedical research.

The California Institute of Technology is one of the world's preeminent institutions for scientific research and its faculty and students are significantly involved in research in biochemistry and molecular biology. The Institute is a private university at which pioneering developments in space technology, radio astronomy, physics, biochemistry and recombinant DNA techniques have occurred.

The American Council on Education is a non-profit corporation organized under the laws of, and located in, the District of Columbia. Founded in 1918, the Council is a membership organization composed of 1,385 non-profit institutions of higher education from both the public and private sectors, many of which are engaged in basic research in biochemistry and molecular biology. The Council's work is financed by membership dues, by grants from foundations and learned and professional societies, and by grants from contracts with the Federal Government. Through its committees the Council has sought to foster patent policies that harmonize college and university research goals with public needs. The Council is the nation's major coordinating body in post-secondary education.

Each Amicus has a fundamental interest in the outcome of this case. Some of the Amici receive contract funds from commercial corporations whose future funding of research in this field is certain to be influenced by this Court's decision. All of the individual Amici receive or plan to receive indirect funding from royalties on patents which are held by their respective universities. The Court's decision in this case will inevitably have a substantial impact on the financing of research at academic institutions, on the way in which research in the laboratories of these Amici is financed, and on the probability that research of these Amici will be commercially developed so as to find useful, lifesaving and life-improving application.

Though engaged primarily in basic research, Amici have an interest in seeing their work reach commercial development. They fear that adoption of a *per se* rule excluding all living things from patentability will inhibit commercial development of the advances they are making in recombinant DNA research. Such inhibitions will occur because the incentive to follow through on many scientific advances, so that they will be commercially useful, will be lacking without appropriate financial incentives. For example, it is a scientific breakthrough to clone the interferon gene in a bacterium. However, to maximize the production of interferon from such a modified bacterium will require a great deal of additional scientific expertise which will not be forthcoming without the protection and rewards that patents provide to the scientific investigator and to the commercial sources which normally fund such work. Even more than in other fields of endeavor, the industrial use of microorganisms is dependent upon patent protection since the "machinery" used in this industry, newly constructed bacteria, are self-reproducing. Once a bacterium which costs millions of dollars to produce is released into the environment—e.g., dropped onto an oil spill—it can be reproduced for pennies. Thus, without the protection of a patent, the developer of a new bacterium will be hard-pressed to recoup his substantial investment.

The fact that patent protection is a prerequisite to commercial development has been clearly documented in connection with past developments in biomedical research.³ For this reason, the Department of Commerce has emphasized the need to grant patent protection to the fruits of recombinant DNA research. The Assistant Secretary of Commerce for Science and Technology stated:

"We must either preserve proprietary rights in the innovations which flow from the [recombinant DNA] research, or we must insist that the government itself undertake to do what private industry now does—bring these innovations all the way to the market place."⁴

Amici request this Court to take notice of the potential benefits to be derived from recombinant DNA technology, and the fact that denying patent protection in this case will adversely impact these potential benefits.

STATEMENT OF THE CASE

Amici Curiae consider that certain procedural aspects of this case were insufficiently underscored in Petitioner's statement and may be relevant to the Court's disposition of the

³ In 1976, the President's Biomedical Research Panel reported evidence of a clear link between the need to protect intellectual property rights and the successful transfer of research innovations to the delivery of health care. "Disclosure of Research Information," June 30, 1976, DHEW Publication No.(os) 76-513.

A GAO Report entitled "Problem Areas Affecting Usefulness of Results of Government Sponsored Research in Medicinal Chemistry" reached the same conclusion. *GAO Report*, No. B-164031. That Report found that from 1962 to 1968, industry virtually boycotted the development of drugs from new discoveries and basic research because of doubts about the availability of patent protection.

⁴ Recombinant DNA Research Act of 1977: *Hearings on H.R. 4759 and 4849 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. 241 (1977) (Statement of Betsy Ancker-Johnson).

question before it. The Patent Examiner rejected the claims in question not on the ground that they were "living organisms," but because they were products of nature (Pet. App. H, 166a-167a). This first ground was introduced *sua sponte* by the Board of Patent Appeals (Pet. App. G, 159a). The patent applicant objected to the Board relying on this previously unargued ground without a remand to the Patent Examiner for a threshold determination on this issue. The Board granted the applicant's request for reconsideration "to the extent of reconsidering our prior decision," but denied it "with respect to making any changes therein," holding as follows:

"We do not agree with appellant that our decision amounts to a new ground of rejection; on the contrary, the statutory basis for both the Examiner's rejection and our affirmance is 35 USC 101 as explained at the top of page 2 of our decision of May 20, 1976" (Pet. App. I, 168a-169a).

SUMMARY OF ARGUMENT

On the sole question before the Court—Are living things unpatentable *per se*?—we agree with the Court of Customs and Patent Appeals ("CCPA") that living organisms are not *per se* unpatentable under Section 101, 35 U.S.C. 101.⁵

Living things are ordinarily not patentable, not because they are alive, but because they are almost always "products of nature." Products of nature are not "inventions" and for that reason are excluded from the definition of patentable subject matter set forth in Section 101.

In 1930 plant hybrids were perceived to be products of nature, not inventions. The Plant Patent Act was enacted to extend patent coverage to these products of nature. Its

⁵ Amici disagree with the Commissioner and the CCPA as to the purpose of this Court's remand in light of *Parker v. Flook*, 437 U.S. 584 (1978), with their reading of the Plant Patent Act of 1930, 35 U.S.C. 161, *et seq.* and the Plant Variety Protection Act of 1970, 7 U.S.C. 2321 *et seq.*, and also with their interpretation of Section 101.

enactment does not support the inference that the Commissioner draws—that plants were unpatentable solely because they were alive. Similarly, the Plant Variety Protection Act extended patent-like protection to certain sexually reproduced plant hybrids, otherwise unpatentable as products of nature.

Thus, Congress has not impliedly expressed its will that living things be unpatentable *per se*. Assuming that the other conditions of patentability are met, new strains of bacteria constructed by the techniques of modern molecular biology are within the bounds of patentable subject matter. Although Congress in 1793, when the predecessor of Section 101 was enacted, did not have transformation or recombinant DNA in mind, Congress has expressed its intention to bestow patents upon the fruits of such new and useful technologies. Moreover, when Congress has determined that other considerations of the public interest outweigh the public interest in providing an incentive for new research, it has known how to exclude specific subject matter from patentability. *E.g.*, 42 U.S.C. 2181.

Though for reasons different from those of Petitioner, Amici disagree with the response of the CCPA to the remand of *Parker v. Bergy*, 438 U.S. 902 (1978). The CCPA took the most dramatic and least analytic view possible of this Court's remand for reconsideration in light of *Flook*. Focusing on the quotation from *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972), that there be an appropriate signal from Congress before any extension of the patent laws, the CCPA stated, "To conclude on the light *Flook* sheds on these cases, very simply . . . we find none" (Pet. App. 26a). But the CCPA was incorrect in determining that the only "launching pad for argument" (Pet. App. 20a) based on *Flook* was the *Deepsouth* cautionary language. *Flook* has a more substantial and relevant basis for decision which should have been discussed by the CCPA, but was not. *Flook* is the most recent in a line of cases, including *Gottschalk v. Benson*, 409 U.S. 63 (1972), that seeks to provide guidance concerning the scope of statutory patentability under Section 101. This line of cases, dealing with a

series of frontier developments in science and technology, seeks to ensure that laws of nature, principles of nature, phenomena of nature and products of nature are not patentable under Section 101.

The patent claims before this Court were originally rejected by the Patent Examiner on the ground that they were drawn to a product of nature—the very ground that is at the heart of *Flook*. Only because of the convoluted history of this case is that narrow issue not presented to this Court. Instead, the Court has before it the far-reaching question of whether "living organisms" are patentable subject matter.

We think that a decision on this extraordinarily broad ground is premature and, on this record, unnecessary. An adverse decision on this broad ground would severely restrict the research conducted by Amici and would have severe implications for the mix of incentives currently provided by the federal government for such research. Additionally, the living/nonliving test for patentability proposed by the Commissioner is unworkable; there is no agreement on a workable or meaningful definition of life. We urge the Court, therefore, to remand the case to the CCPA for thorough analysis and decision on the product of nature question, or to dismiss the writ of certiorari as improvidently granted. Alternatively, the decision of the CCPA should be affirmed because the definition of patentable subject matter set forth in Section 101 does not *per se* exclude all living things.

ARGUMENT

I.

GIVEN THE CURRENT RECORD, THE APPROPRIATE COURSE IS TO REMAND THE CASE OR DISMISS THE WRIT OF CERTIORARI AS IMPROVIDENTLY GRANTED

The question before the Court—Are living organisms *per se* unpatentable?—is a question of first impression. The disposition of this question will have far-reaching implications.

Economic incentives for research such as conducted by Amici will be reduced by a rule excluding all living organisms from patentability. Such a rule will adversely affect commercial development of the fruits of the research of Amici, and will also have a negative effect on the competitive stance of American industry in the extremely competitive field of biotechnology.⁶ Furthermore, such a rule would impose an unworkable test for patentability. Scientists agree that the line separating life and non-life cannot be sharply drawn; it is indefinite and even then, arbitrary.

Moreover, the procedural history of this case sets a faulty stage for deciding what is almost a theological issue. A narrower ground of decision—whether the claims at issue are unpatentable as products of nature—is not before this Court, despite the fact that the Patent Examiner relied solely on this ground. After this case was remanded to the CCPA for reconsideration in light of *Parker v. Flook*, 437 U.S. 584 (1978), the product of nature ground for rejection should have been addressed. It was not. Consideration of this question might have eliminated the need to decide if living things are *per se* unpatentable. This case should be remanded specifically for consideration of the product of nature ground. Alternatively, the writ of certiorari should be dismissed as improvidently granted.

A. In Reconsidering This Case In Light Of *Parker v. Flook*, The CCPA Should Have Examined The Product Of Nature Ground

Parker v. Flook, *supra*, is relevant to the disposition of this case because here, as in *Flook*, “the case turns entirely on the proper construction of § 101 of the Patent Act, which describes the subject matter that is eligible for patent protection.” *Id.* at

⁶ See, “Who’s Ahead, Who’s Behind,” 238 *Nature*, 123 (1980). *Nature* notes that of the biotechnological patents delivered since 1977, 124 originated in Japan and 39 in the U.S. It states: “Japan has taken an incontestable lead in biotechnology.” *Ibid.*

588. The basis for inquiry in *Flook*, as in *Gottschalk v. Benson*, 409 U.S. 63 (1972), turned on the following statement in *Benson*:

“‘A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right’. *Le Roy v. Tatham*, 14 How. 156, 175, 14 L.Ed. 367. Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” 409 U.S. at 67.

In *Flook* and in *Benson* this Court attempted to draw the line between what is properly the property of the public as a principle or product of nature, and what is patentable as an invention, *applying* a law of nature to a new and useful end. See also *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).⁷ Interpreting Section 101 to limit patentable subject matter to “inventions,” this Court has been true to an historical recognition that the “rights and welfare of the community must be fairly dealt with and effectually guarded.” *Kendall v. Winsor*, 21 How. 322, 329, 16 L.Ed. 165, 168 (1859).

Flook dealt with an algorithm for which “the line between a patentable ‘process’ and an unpatentable ‘principle’ is not always clear.” *Parker v. Flook*, *supra* at 589. This Court there stated:

“The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processess, but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was enacted to protect. . . .

⁷ The “invention” requirement is not subsumed by Sections 102 and 103, as the CCPA contends (Pet. App. 15a). This Court has expressly rejected that position. *Parker v. Flook*, *supra* at 592-94. Thus, the tests for invention articulated in *Funk*, which predated the 1952 reorganization of the patent statutes, are pertinent to the patentability of the claims at issue. *Id.* at 591-94.

"... [T]he discovery of such a [natural] phenomenon cannot support a patent unless there is some other inventive concept in its application." (Footnote omitted.) *Id.* at 593.

Thus, the Court's remand should have guided the CCPA to look more closely at the line between statutorily patentable inventions, on the one hand, and discoveries of products or phenomenon of nature, on the other, particularly since in this case the patent claims were originally rejected on the ground that they were products of nature.

B. In Order That The Product Of Nature Ground May Be Fully Considered, The Case Should Be Remanded

In view of the foregoing and the unusual procedural context in which this case arises, substantial doubt is raised as to whether these claims present an appropriate vehicle for more than an advisory opinion on the fundamental question of the *per se* exclusion of living organisms from patentability under Section 101.

There is some question whether the Board of Appeals, which first introduced this question into the record, can add a ground for rejection without addressing the specific ground cited by the Patent Examiner.⁸ In its discussion of the procedural context on remand from this Court, the CCPA, with respect to *Bergy*,⁹ asserted that a new ground had been added and that

⁸ See 37 C.F.R. § 1.196(d) which provides that the Board of Appeals "normally will confine its decision to a review of rejections made by the primary examiner. . . ." If it believes another ground should be included, "the Board shall set a period, not less than one month, within which the applicant may submit to the primary examiner an appropriate amendment, or a showing of facts or reasons, or both, in order to avoid the grounds set forth in the statement of the Board of Appeals." The record does not indicate that this procedure was followed in this case apparently because the Board of Appeals thought it was not substituting a new ground for rejection (Pet.App. I, 168a).

⁹ We recognize that the Court has remanded the *Bergy* case to the Court of Customs and Patent Appeals and has directed that it be dismissed as moot. We refer to *Bergy* here only to the extent necessary fully to explicate the case at hand.

"we have an anomalous situation here in that the Board affirmed on a *new* ground without so stating, not reaching the *sole* ground relied on by the examiner" (Pet. App. 39a). In *Chakrabarty*, the Board of Appeals asserted that it had not added a new ground for rejection (Pet. App. I, 168a), although the record clearly demonstrates that the Patent Examiner relied solely on the product of nature ground (Pet. App. H, 166a-167a).

We set forth this procedural framework to indicate the peculiarity of the case as it reaches this Court. The Commissioner has abandoned the very ground for rejection that is most relevant to the *Flook* analysis and seeks only to reverse the CCPA's decision that living things may be patented.¹⁰ Because the Commissioner failed to assert the product of nature ground before the CCPA, there is no one with standing to press it to this Court. Amici are concerned that the Court may find itself reaching a largely abstract issue not ripe for decision because of the procedural oddities of this case.¹¹

Remanding for closer analysis of this difficult question—i.e., the proper interpretation of the product of nature limitation—is consistent with *Flook* and *Benson*, as well as with

¹⁰ In the first *Chakrabarty* CCPA decision, Judge Baldwin, dissenting, would have held that "this improvement in the utility for which the unpatentable starting material was already suited does not change the essential nature of the starting material and does not make the modified thing statutory subject matter" (Pet.App. F, 154a). Thus, Judge Baldwin would have decided the question on product of nature grounds and would have held, essentially, that the *Chakrabarty* claims were not sufficiently "modified" (Pet.App. F, 152-154a).

¹¹ Amici do not take any position as to whether *Chakrabarty*'s claims are "products of nature" as the Patent Examiner found. In any case, *Chakrabarty*'s discovery employed only first generation "transforming" techniques which are less sophisticated than classical recombinant DNA techniques, which involve complex chemical surgery to cut long threadlike DNA molecules into pieces. The resulting segments of DNA are recombined with the DNA of a suitable bacteria and then reinserted into the bacteria to propagate and function.

earlier cases reflecting this Court's analysis of the meaning of the "invention" requirement.¹²

A new remand to the CCPA for a more definitive answer to this question—even if it entails a further remand from the CCPA to the PTO¹³—is far more consistent with Section 101 and with this Court's prior decisions than would be a ruling on the abstract question as to whether "living organisms" can be patented.

C. A Living/Non-living Test For Patentability Would Be Unworkable And Scientifically Meaningless

The Commissioner proposes that future decisions as to patentability be made on the basis of whether or not the claimed invention is alive. Such a standard would be unworkable. There is no distinct line between life and non-life.

The prevailing view among scientists is that the essential characteristic of "living" matter is nothing more than its complexity. "Life is not one of the fundamental categories of the universe, like matter, energy and time but is a manifestation of certain molecular combinations." N. H. Horowitz, F. D. Drake, S. L. Miller, L. E. Orgel and C. Sagan, "The Origins of Life" from *Biology and the Future of Man*, 165 (P. Handler, Ed. 1970).

Nobel Laureate Erwin Schrodinger argues that the transition from atoms to molecules, to giant molecules such as enzymes, to simple viruses and on up to bacteria is a continuum. At some arbitrary level the aggregates take on sufficient complexity that they are regarded as living. E. Schrodinger, *What Is Life* (1958).

¹² E.g., *O'Reilly v. Morse*, 15 How. 62, 14 L.Ed. 601 (1853); *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86 (1939); *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, *supra*.

¹³ Katz, Examiner in Chief, dissenting in the Board of Appeals decision in the *Bergy*, case would have remanded to the Examiner for a fuller record on this issue (Pet.App. D, 139a).

Not only is the line between living and inert matter arbitrary, it is also likely to be redrawn as a result of recent research in molecular biology. For example, scientists have recently discovered an entity called 'viroid'. Viroids consists only of a closed circular chain of RNA, but are nevertheless infective and act in other ways like a living virus.¹⁴ S. E. Lauria, J. E. Darnell, Jr., D. Baltimore, Allan Campbell, *General Virology* (1978).

Thus, the living/non-living test for patentability proposed by the Commissioner is unworkable. Moreover, there is no scientific significance in the proposed test. A more workable test is to exclude products of nature from patentability. This standard, although not completely free of arbitrariness,¹⁵ is derived, at least, from the long-standing statutory requirement of "invention."

D. Alternatively, The Writ of Certiorari Should Be Dismissed As Improvidently Granted

This Court has dismissed a writ of certiorari as improvidently granted where the issue of importance was not "presented with sufficient clarity," *Kimbrough v. United States*, 364 U.S. 661 (1961), or where the fundamental question was not presented on a record "sufficiently clear and specific" to permit decision of the issues presented in the petition. *Massachusetts v. Painten*, 389 U.S. 560, 561 (1968).

The fundamental question presented to this Court—Are living things *per se* unpatentable?—is not fully developed. The implications of imposing such an arbitrary and unworkable

¹⁴ The question of whether a virus should be considered as "living" is also disputed. The accepted view is that viruses can be characterized as both "exceptionally simple microbes and as exceptionally complex chemicals." B.D. Davis, R. Dulbecco, H.N. Eisen, H.S. Ginsberg, W.B. Wood, Jr., *Microbiology* 1014 (2d Ed. 1973).

¹⁵ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, *supra* at 132-35 (Frankfurter, J., dissenting).

standard have not been explored. The Patent Examiner has not been given a chance to even consider this ground. Thus, there have been no factual findings pertinent to the question before this Court.

Moreover, the preferred and more limited ground for decision, namely, whether or not the applicant's claim presented a "product of nature," was not before the CCPA. Because the Commissioner abandoned that ground after the Board's decision, the only question before this Court is whether a "living organism" is patentable under Section 101. Where an independent and narrower ground for decision is conceivably available, this Court should avoid such questions of first impression, particularly where presented on an incomplete record. Thus, if a second remand is not appropriate, the writ of certiorari should be dismissed as improvidently granted. Undoubtedly, the question will soon be brought back to this Court, but perhaps then on a complete record with all preliminary questions dispositively decided.¹⁶

We recognize that dismissal of a writ of certiorari is extraordinary and atypical. But given the record in this case, and the status of the issues before this Court, we think that such a disposition is consistent with this Court's remand of *Bergy* in light of *Parker v. Flook*.

¹⁶ An alternative disposition would be to affirm the decision of the CCPA, but with an opinion that suggests the need to look more critically, and perhaps more expansively at the definition of "product of nature." Because the Commissioner appears bound by the Board's determination that *Chakrabarty's* claim did not involve a "product of nature," that ground has not been brought before this Court. Nonetheless, an affirmance by this Court does not determine the ultimate validity of the claims at issue because of potential private actions. Appeals reaching this Court from decisions of the CCPA and the Patent Office are different from appeals in an inter partes private action, such as an action for infringement or for invalidity of the patent, in which a private litigant would undoubtedly include among the arguments the very ground for rejection relied on by the Patent Examiner in this case.

II.

IF IT IS NECESSARY TO REACH THE MERITS, THE DECISION OF THE CCPA SHOULD BE AFFIRMED

If this Court reaches the merits of the CCPA's decision below, the CCPA should be affirmed. Living organisms are not *per se* excluded from patentability.

The Commissioner argues that Congressional intent to *per se* exclude living things from patentability can be inferred from historical facts: (1) That Congress, in enacting the predecessor of Section 101, failed to include living things in its list of patentable subject matter; (2) That in 190 years the case before the Court is the first to raise the issue that living things are patentable;¹⁷ and (3) That enactment, in and of itself, of the Plant Patent Act of 1930, 35 U.S.C. 161 *et seq.*, and the Plant Variety Protection Act of 1970, 7 U.S.C. 2321 *et seq.*, demonstrates a Congressional intent to exclude all living things, with the exception of plants, from patentability.

Congress possesses the authority to bestow patents upon living things. In enacting the predecessor of Section 101 in 1793, Congress meant only to limit patentable subject matter to "new and useful inventions," and did not *per se* exclude all living things. The passage of the Plant Patent Act and the Plant Variety Protection Act do not create a contrary inference. Those acts were passed because Congress believed many plant hybrids to be "products of nature," and hence unpatentable for that reason and not because they were alive.

A. Congress Has The Constitutional Authority To Bestow Patent Protection On Living Things

There has been no contention that a patent on a living organism would be unconstitutional. The Constitution granted Congress broad authority to reward inventions and discoveries:

¹⁷ Amici do not undertake specifically to rebut this argument. Every issue must arise for the first time. Moreover, only the recent advances in biology have made it possible to create new living organisms, such as the bacteria at issue, and thus give rise to the question before the Court.

"The Congress shall have power . . . [8] To promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . . And [18] To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers" *U.S. Const.* art. I, sec. 8.

The Commissioner does not dispute that this broad grant of authority empowers Congress to bestow patents upon living things. Moreover, fifty years of the Plant Patent Act demonstrate universal acceptance of the constitutionality of patents on plants. In fact, the Fifth Circuit Court of Appeals has recognized the constitutionality of the Plant Patent Act, notwithstanding the fact that it provides for the patentability of living things. *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1382 (5th Cir. 1976).

Thus, if this Court considers the broad question of the patentability of living organisms, the only issue is whether Congress exercised its authority in such a manner as to permit patents on living things, subject of course to the ordinary requirements for patentability. In other words, in enacting the predecessor of the current patent statutes, did Congress exclude from patentability all living things?

B. The Historic Breadth Of The Statutory Patentability Standard Is Inconsistent With Implied Exclusion

As the Commissioner points out (Pet. Brief at 13), the predecessor of the current Section 101 was enacted almost 190 years ago and is only slightly changed since then. That statute defined patentable subject matter as "any new and useful art, machine, manufacture, or composition of matter." Petitioner argues that the failure of Congress to include living things within its listing of patentable subject matter creates an inference that no living thing is patentable.¹⁸

¹⁸ To support this inference the Commissioner relies on this Court's holdings, in other areas, that the patent monopoly be strictly construed. But the cases relied on by the Commissioner are inapposite. In *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518,

(Footnote continued on following page)

Petitioner's argument mocks Congressional purpose. Strictly construing the scope of patentable subject matter to exclude all things not contemplated by Congress in 1793 would undermine the entire patent system. Congress intended patents to be bestowed on *new* discoveries and inventions. In fact, patent protection is available only if the invention was not obvious to one skilled in the art. *Hotchkiss v. Greenwood*, 11 How. 248, 13 L.Ed. 683 (1851); 35 U.S.C. 103. Thus, Congress could not have expected that it had foreseen all new inventions and provided for their patentability. Rather, as this Court has previously held:

"The true policy and ends of the patent laws . . . are disclosed in that article of the Constitution, . . . viz.: 'to promote the progress of science and the useful arts,' contemplating and necessarily implying their extension, and increasing adaptation to the uses of society." *Kendall v. Winsor*, *supra*, 21 How. at 328, 16 L.Ed. at 168.

Congress did not intend to impose a static definition of patentability, limited by the fields of endeavor existing in 1793. Instead, Congress intended to grant a limited monopoly for those inventions which "serve the ends of science—push back the frontiers of chemistry, physics, and the like; and make a distinctive contribution to scientific knowledge." *Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147,

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530-31 (1972), this Court was concerned only with whether the patent laws should be given extraterritorial effect. Strict construction limiting the patent monopoly to the United States is quite different than a strict construction excluding new technologies. The 1952 Congress could foresee export of United States manufacture, but the 1793 Congress recognized that it could not foresee all technological advances.

In *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 232 (1964), the patentee was attempting to secure a monopoly on an unpatentable item by asserting rights under a State's unfair competition laws. In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Court articulated the test for "obviousness" to be applied under Section 103. At page 7, as cited by Petitioner, this Court discussed Thomas Jefferson's aversion to monopolies, which later ripened into support for the patent system. In fact, Jefferson drafted the 1793 Patent Act. *Id.* at 10.

154 (1950) (Douglas, J., dissenting). As a recent Congress has stated, the listing in Section 101 of statutory subject matter is not restrictive, but "may include anything under the sun that is made by man." H.R. Rep. No. 1923, 82nd Cong., 2d Sess. 6 (1952); S. Rep. No. 1979, 82nd Cong., 2d Sess. 5.

Perhaps it is the Commissioner's position that living things are *per se* excluded from patentability because, in the government's view, they do not satisfy classic definitions of "machines," "manufactures" or "compositions of matter."¹⁹ Whether the Commissioner relies on this basis for excluding "living things" from patentability or on the ground that they are not inventions is unclear from the government's argument. The cases dealing with these subject matter categories demonstrate that certain living things do in fact fall within them.

Bacteria such as those constructed by techniques of recombinant DNA are clearly new compositions of matter. A patentable composition of matter results from the mixing of two or more ingredients to produce a product with different or additional properties not possessed individually by the ingredients. *P. E. Sharpless Co. v. Crawford Farms, Inc.*, 287 F. 655, 658 (2d Cir. 1923). "There is no restriction as to the nature of the composition which may be patented." *Ibid.* Recombinant DNA techniques, which break DNA chains and remove and/or insert new segments into the DNA of an existing bacterium are used to construct strains which possess properties not found in naturally occurring bacteria.

¹⁹ Amici recognize that "[t]he plain language of § 101 does not answer the question" as to the full scope of Section 101. *Parker v. Flook*, *supra* at 588. However, analysis of judicial interpretation of the four categories of invention demonstrates that new bacteria created by techniques of recombinant DNA are well within the bounds of Section 101.

Some bacteria are also manufactures. This Court has required that a manufacture differ from the raw materials used to make it by possessing "a new or distinctive form, quality, or property." *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931).²⁰ The *Pseudomonas* developed by Dr. Chakrabarty possess a new quality or property; they can decompose more than one component of crude oil, a quality possessed by no other bacterium (Pet. App. 30a-31a).²¹

Thus, Congress did not mean to exclude all living things from patentability simply by failing, in 1793, specifically to include "living" machines, manufactures, or compositions of matter within its definition of statutory subject matter. Congress did, however, impose a requirement that patents be bestowed only on "inventions." This standard excludes from patentability "[p]henomena of nature, . . . mental processes, and abstract intellectual concepts." *Gottschalk v. Benson*, *supra* at 67. As we shall see, this standard had been applied, prior to passage of the Plant Patent Act, to exclude plants from patentability under Section 101.

²⁰ The orange with borax-treated rind at issue in *Brogdex* was not patentable because it remained a product of nature; the borax treatment did not change any of its essential characteristics. Had such a change been realized, all implications of the opinion favored patentability; there was no mention of a *per se* exclusion of all living things.

²¹ Bacteria can also, by means of recombinant DNA technology, be made to produce human insulin. Bacteria occurring in nature do not possess this capacity.

A bacterium might also be characterized as a machine. In 1853 this Court understood the term "machine" to include "every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." *Corning v. Burden*, 15 How. 252, 267; 14 L.Ed. 683, 690 (1853). This term is understood today to include devices which utilize chemical and electrical processes, as well as those utilizing mechanical means. By means of chemical processes which occur inside bacteria, bacteria operate as machines to "produce a certain effect or result."

C. The Passage Of The Plant Patent Act And The Plant Variety Protection Act Does Not Support An Inference That Congress Intended Living Things To Be *Per Se* Unpatentable

The Commissioner places great reliance on certain inferences which he alleges can be drawn from the Plant Patent Act. We agree with the Commissioner that in 1930 plants were unpatentable and the Act was necessary to extend patent protection to plants. However, plants were unpatentable, not because they were alive, but for reasons related to our interpretation of Section 101. Many hybrids extended protection under the Plant Patent Act would have been considered "products of nature" under Section 101 and would therefore have been unpatentable.

Petitioner's argument that passage of the Plant Patent Act and the Plant Variety Protection Act creates an inference that Congress in 1793 intended to exclude all living things from patentability begins with the premise that the plain language of the statutes reveals this conclusion. It does not. The passage and language of the plant acts are entirely consistent with the position of Amici—that many plant hybrids were unpatentable because they were products of nature.

To support the inference he would draw, the Commissioner relies on scattered statements taken out of context from the legislative history and on a statement by Secretary of Agriculture Hyde. These statements ignore the thrust of Congressional concern.²²

²² As the principal House sponsor Representative Purnell noted, the bill presented issues "that few are competent to discuss, but the Commissioner of Patents has given this very, very careful study." 72 Cong. Rec. 8392 (1930). As we shall see, the Commissioner of Patents understood that plants were generally unpatentable because they were products of nature and not because they were alive.

Moreover, it may well be that Secretary Hyde suggested that plant hybrids were unpatentable not because they were alive, but because they were products of nature. His reference to the

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Representative Purnell, the Act's principal House sponsor, recognized that plants were not "inventions" because in most cases man merely selected a new and desirable hybrid from a field. The hybrid was created by natural processes, without man's creative invention. He carefully distinguished between "plant developers" and "industrial inventors," and recognized that the patent laws also distinguished between the two. *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 2 (1930).²³ Similarly, both the House and Senate committees distinguished between plant developers and industrial inventors, and recognized that the patent law did also.²⁴

From Congressional descriptions of the plants covered by the Plant Patent Act it is readily apparent that the great majority of newly developed hybrids were, prior to passage of

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unpatentability of living things might well have been a shorthand reference to an argument he developed more fully in the same letter upon which the Commissioner so heavily relies:

"... the words 'invented' and 'discovered' . . . shall be interpreted to include invention and discovery in the sense of finding a thing already existing and reproducing . . . ' [These words,] interpreted in the light of agricultural and horticultural experience and history, would appear to make possible the patenting . . . of any new and distinct variety wherever discovered. . . ." H.R. Rep. No. 1129, 71st Cong., 2d Sess. Appendix A (1930); S. Rep. No. 315, 71st Cong., 2d Sess. Appendix A (1930).

²³ The Petitioner, by contrast, cites a letter from Edward Rumeley, of New York City, to which he holds Representative Purnell to have concurred, because Representative Purnell read the letter into the record. The weight to be given this letter is reduced even further when one notes that Mr. Rumeley was apparently quoting from a news article. *Id.* at 4.

²⁴ "The bill will remove existing discrimination between plant developers and industrial inventors." H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930).

the Act, unpatentable products of nature.²⁵ Congress understood that man did not cause the creation of the new hybrid, he merely arranged to have nature work in his fields, where he could detect the creation of new varieties. Man's involvement was limited to assisting pollenization; in some cases, *e.g.* sports and mutants, man did nothing but recognize that the new plant which appeared in the cultivated field was useful, or otherwise distinctive. In all instances these plants were referred to as "bred" or "cultivated."²⁶

Many, if not all of these newly cultivated plants were unpatentable as products of nature under the controlling case law existing prior to 1930. For, as this Court held in 1885, patents are to be awarded only for "the creative work of . . . inventive faculty." *Hollister v. Benedict & Burnham Mfg. Co.*, 113 U.S. 59, 73 (1885). In fact, the same test for invention continues to be applied today, except in the case of plant patents. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, *supra* at 131.²⁷

²⁵ "In the first class of cases, the sports, the new and distinct variety results from bud variation and not seed variation. A plant or portion of a plant *may suddenly assume* an appearance or character distinct from that which normally characterizes the variety of species.

"In the second class of cases, the mutants, the new and distinct variety results from seedling variation *by self pollenization* of species.

"In the third class of cases, the hybrids, the new and distinct variety results from seedlings of cross pollenization of two species, two varieties, or of a species and a variety." (Emphasis added.) H.R. Rep. No. 1129, *supra* at 4; S. Rep. No. 315, *supra* at 3.

²⁶ *Hearings on H.R. 11372, supra*, at 3; H.R. Rep. No. 1129, *supra* at 1, 2, 3, 4, 5, 8, Appendix A.

²⁷ As one commentator has noted:

"Every invention which can be patented involves a discovery of some sort, but it is not every discovery that can be patented.

"The general distinction between the words is that discovery relates to phenomena, laws, or things which already existed, but which had not been perceived before, whereas invention relates to things which did not exist before." *The Law of Chemical, Metallurgical and Pharmaceutical Patents* 61 (Forman, Ed. 1967).

Before enacting the Plant Patent Act Congress considered the objection raised by Commissioner of Patents Robertson that the Constitution did not empower Congress to bestow patents on plants because plants were products of nature, not inventions.²⁸ Congressional discussion of this objection further evidences the belief of Congress that plants were then unpatentable because they were products of nature, not merely because they were alive.

Congress responded to the objection in the Reports submitted by the committees in the House and Senate. First, the broad Constitutional authority of Congress to bestow patents on "finds" not created or invented was documented.²⁹ Next, Congress expressed its belief that man was sufficiently involved

²⁸ Briefly, the Commissioner of Patents then argued that:

" . . . [I]n passing such a bill Congress may be exceeding the powers granted by the Constitution. This is particularly so with respect to the provision . . . which permits patents to be granted . . . for a 'thing already existing' . . .

"The courts have uniformly held that a valid patent can be granted only for an invention. In the case of *Thompson v. Boisselier* (114 U.S. 1) the Supreme Court of the United States said that the [patentee] . . . must be 'an inventor and he must have made a discovery,' . . .

"It may be doubted whether a valid patent can be granted for a plant even if it is a new variety, *when that plant is reproduced by operation of nature, aided only by the act of the patentee in grafting it by the usual methods.* . . ." (Emphasis added.) *Hearings on H.R. 11372, supra* at 6.

²⁹ "At the time of the adoption of the Constitution the term 'inventor' was used in two senses. In the first place the inventor was a discoverer, one who finds or finds out. In the second place an inventor was one who created something new. All the dictionaries at the time of the framing of the Constitution recognized that 'inventor' included the finder out or discoverer as well as the creator of something new. . . .

"[I]t is reasonable to suppose the framers of the Constitution attributed to the term 'inventor' the then customary meaning." H.R. Rep. No. 1129, *supra* at 8-9; S. Rep. No. 315, *supra* at 8.

in the cultivation of certain new plants so as to bring patents on those plants within Constitutional bounds.³⁰

Thus, Congress traced its path carefully so as to bestow patents on certain covered plants—theretofore products of nature—without extending beyond its constitutional authority.³¹ The Reports of both committees emphasized in closing that the Act was intended to expand the definition of invention:

“As to patents the doubt is only as to the one word, ‘inventors.’ . . . It is not to be expected that the courts would place themselves in the position of impeding the progress of the science and useful art[s] . . . by holding to so narrow a definition of the word ‘inventor’ . . .” H.R. Rep. No. 1129, *supra* at 10; S. Rep. No. 315, *supra* at 9.

³⁰ “There can be no doubt that the grant of plant patents constitutes a promotion of ‘the progress of science and useful arts’ within the meaning of the constitutional provision. The only question is, is the new variety a discovery and is the originator or discoverer an inventor?”

“There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such as a new and useful mineral. The mineral is created *wholly by nature unassisted by man*. . . . On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature *unaided by man*. . . .

“It is obvious that nature originally creates plants but it can not be denied that man often controls and directs the natural processess and produces a desired result. In such cases the part played by nature and man cannot be completely separated. . . . Nature . . . unaided by man, does not reproduce the new variety true to type.” (Emphasis added.) H.R. Rep. No. 1129, *supra* at 7; S. Rep. No. 315, *supra* at 6-7.

Petitioner also argues that by 1970 new varieties of plants were created by altering genetic structure chemically or with radiation. Changes so induced are not predictable. These techniques do nothing more than speed up nature’s own mutation processes. Thus, chemicals and radiation did not significantly alter the 1930 relationship of man and nature.

³¹ New plants found by explorers were excluded from the Act, not because they alone were unpatentable products of nature, but because such discoveries did not require the financial incentives provided by the patent system. H.R. Rep. No. 1129, *supra* at 1-2; S. Rep. No. 315, *supra* at 1-2.

With the possible exception of Secretary Hyde’s “inanimate” comment, this view of Congressional understanding and intention is wholly supported by the legislative history of the Plant Patent Act.³² Congress did not believe plants were unpatentable prior to passage of the Act simply because they were alive.

III.

A *PER SE* RULE EXCLUDING LIVING ORGANISMS FROM PATENT PROTECTION WOULD BE IMPROPER IN LIGHT OF THE ONGOING CONGRESSIONAL AND EXECUTIVE ACTIONS DIRECTED TOWARDS MAXIMIZING THE DEVELOPMENT AND APPLICATION OF DNA TECHNOLOGY

Petitioner argues that patent protection for living organisms should await “‘a clear and certain signal from Congress.’” *Parker v. Flook*, *supra* at 596. Amici do not believe that the Court must search for a “signal” in the *Deepsouth* sense, to determine whether Section 101 should be interpreted to exclude all “living organisms.”³³ But if the Court seeks such a signal, we believe that it exists in recent Congressional and executive actions pertaining to recombinant DNA.

Most of the Congressional activity in this area has been directed towards minimizing the potential safety hazards of recombinant DNA.³⁴ This inquiry has, however, taken place

³² The Plant Variety Protection Act merely extended patent-like protection to certain sexually reproduced plants. Standing alone it creates no inference that living things are *per se* unpatentable.

³³ When Congress has determined that certain subject matter should not be patented it has had no difficulty in enacting the appropriate legislation. For instance, it has determined that the incentive for invention was outweighed by other considerations of the public interest and has enacted legislation rendering inventions unpatentable to the extent they are used in the utilization of special nuclear material or atomic energy in atomic weapons. 42 U.S.C. 2181.

³⁴ See, e.g., the Recombinant DNA Research Act of 1977 (H.R. 4759; H.R. 4849; 95th Cong., 1st Sess.) and the DNA Research Act of 1977 (H.R. 3191; H.R. 3591; H.R. 3592; H.R. 5020; 95th Cong. 1st Sess.). These bills would have instructed the Secretary of Health, Education and Welfare to enact safety regulations for DNA research.

against a backdrop which assumes present patentability. *See, e.g., 2 Recombinant DNA Research: Documents Relating to NIH Guidelines for Research Involving Recombinant DNA Molecules*, DHEW Pub. No. (NIH) 78-1139 (1978) at 21. The Patent and Trademark Office itself promulgated new regulations to expedite examination of related patent applications to encourage the dissemination of information in the recombinant DNA field.³⁵ Even where restrictive legislation imposing mandatory safety standards has been proposed, *see* H.R. 3191, 95th Cong., 1st Sess. (1977), it explicitly assumes the continuation of patentability, conditioning awards on adherence to future guidelines.³⁶

Obviously, there are legitimate safety concerns, but these continue to be addressed, as they must, independent of the question of patentability. The National Institutes of Health, which has significant responsibility for financing basic biomedical research,³⁷ has enacted and recently revised guidelines governing recombinant DNA research.³⁸ Restrictions on patentability of the sort suggested here by Petitioner are totally inadequate proxies for the careful and systematic approach to safety protection being taken by the NIH and the scientific community.³⁹

³⁵ *Recombinant DNA: Accelerated Processing of Patent Applications For Inventions*, 42 Fed. Reg. 2712 (1977). These regulations were withdrawn. The practice was initiated at the request of the Assistant Secretary of Commerce for Science and Technology.

³⁶ For example, Section 6 of H.R. 3191 would have provided "notwithstanding any other law, no patent shall be granted on any procedure or organism which results from research on recombinant DNA unless all applicable guidelines have been strictly adhered to, and full and complete disclosure has been made with regard to such process or organism.

³⁷ NIH is providing approximately \$102,000,000 in grants each year for basic research in this area.

³⁸ *Recombinant DNA Research: Revised Guidelines*, 43 Fed. Reg. 60080, 60108, 60134 (1978).

³⁹ In these very cases, for example, the process claims themselves were found valid even though the product claims were not.

CONCLUSION

For the foregoing reasons, this action should be remanded to the Court of Customs and Patent Appeals or the writ of certiorari dismissed as improvidently granted. Should this Court reach the merits, the judgment of the Court of Customs and Patent Appeals should be affirmed.

January 28, 1980

Respectfully submitted,

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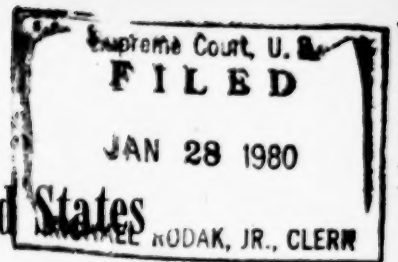
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IN THE
Supreme Court of the United States



October Term, 1979
No. 79-136

SIDNEY A. DIAMOND, Commissioner of Patents and
Trademarks,

Petitioner,

vs.

ANANDA M. CHAKRABARTY.

**BRIEF ON BEHALF OF GENENTECH, INC.,
AMICUS CURIAE.**

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"Where Genetic Engineering Will Change Industry", Business Week, Oct. 22, 1979, pp. 160, 164, 172	10, 15

Statutes

Animal Welfare Act of 1970, 7 U.S.C. 2131	12
Animal Welfare Act of 1970, 7 U.S.C. 2132(g)	12
Plant Patent Act of 1930, 35 U.S.C. 161	12, 21
Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542, 7 U.S.C. 2321	21
United States Code, Title 7, Sec. 182(3)	12
United States Code, Title 19, Sec. 1337	19
United States Code, Title 19, Sec. 1337a	19
United States Code, Title 35, Sec. 101	9, 12, 21, 22
United States Code, Title 42, Sec. 2181(a)	5, 8, 9

IN THE
Supreme Court of the United States

October Term, 1979
No. 79-136

SIDNEY A. DIAMOND, Commissioner of Patents and
Trademarks,

Petitioner,

vs.

ANANDA M. CHAKRABARTY.

**BRIEF ON BEHALF OF GENENTECH, INC.,
AMICUS CURIAE.**

*"'Is it conceivable' I asked, 'that one day we shall create, in effect, biological machines—systems that can be used for productive purposes and will be composed not of plastic or metal parts, but of living organisms?' His answer was . . . unequivocal: 'We are already there. The great future of industry will come from biology.'"*¹

Interest of Amicus Curiae.

Genentech is a small venture capital corporation founded in California in 1976 to convert the promise of recombinant DNA technology into received benefits in areas as diverse as medicine, agriculture and energy. Research funded by Genentech at the City of Hope

¹Toffler, *Future Shock*, 195 (Bantam ed., N.Y. 1970), reporting a conversation with Arne Tiselius, president of the Nobel Foundation.

National Medical Center in Duarte, California and elsewhere resulted in the creation, for the first time anywhere, of a bacterial organism capable of producing a human hormone. In subsequent testimony before Congress that achievement was hailed as a "scientific triumph of the first order" by Phillip Handler, president of the National Academy of Sciences, and as "astonishing" by Paul Berg, himself a pioneer in the field.²

More recently, Genentech and its City of Hope collaborators succeeded, with other genetically altered bacteria, in producing no less than human insulin itself. Press reaction included this, from the September 8, 1978 editorial pages of the *Los Angeles Times*:

"The important and laudable achievement in insulin copying supports the positive expectations of scientists to the potential benefit of millions of persons now living and yet to be born."

And in July of 1979, in what *The Economist* hailed as a "remarkable feat"³, Genentech married natural and synthetic DNA to create a microorganism capable of producing human growth hormone. The result will be unlimited availability of a substance heretofore in critical short supply for the treatment of dwarfism and, possibly, one useful for bone fracture and burn therapy as well.

Variously in collaboration with other private parties, educational institutions and, for that matter, agencies of the United States Government, Genentech is continuing research aimed at the beneficial application

²Hearings on Regulation of Recombinant DNA Research before the House Subcommittee on Science, Technology and Space, 95th Congress 1st Sess. 27, 55 (1977).

³Issue of July 14, 1979 at 88.

of recombinant DNA technology in cancer treatment, in the creation of vaccines against a wide variety of viral diseases, and in other fields.

It should be clear that the issue before this Court transcends the narrow interests of the parties and that the Court's decision will have a profound impact on, for example, the question whether investments in research expenditures and recombinant DNA technology should be made in view of the character of patent protection available. In Genentech's case the patent incentive did, and doubtless elsewhere it will, prove to be an important if not indispensable factor in attracting private support for life-giving research. And where the Patent System facilitates the interposition of small but fruitful companies like Genentech in pharmaceutical and other industries traditionally dominated by major concerns, it operates to best purpose, as an essentially pro-competitive mechanism.

Having delivered very substantial benefits to the public in reliance on the patent incentive, Genentech is vitally interested in continued operation of the quid pro quo principle upon which the Patent System is based.

All parties have consented to the filing of this brief Amicus by letter, the originals of which are being filed concurrently with the clerk.

The Issues Presented.

The issues addressed by this amicus are:

Whether it is in the public interest to afford patents on newly manufactured microorganisms;

Whether, in the alternative, any public interest could be served by denying them; and

Whether it is appropriate for this Court, before Congress has acted, to essay the task of subtracting any particular technology from the compass of a patent statute plainly written to embrace technologies unknown to Congress at the time of passage.

In the view of this amicus, and particularly following the dismissal of *Diamond v. Bergy*, No. 79-136 as moot, the issue before the Court is decidedly not one of patenting either principles of nature or anything akin to them. Compare *Parker v. Flook*, 437 U.S. 584 (1978). The Chakrabarty microorganism, like those created by Genentech, is remarkable precisely because it is found nowhere in nature. Instead, at least in respect to what makes it useful, it was called into being solely by the hands of man.

Summary of Argument.

American experience has shown that the Patent System of the United States is one of the most ingenious engines for the inspiration of new technology ever conceived. In large part, the ingenuity of the system is attributable to two of its special characteristics.

First, the system seeks not to catalogue the past, but rather to compass the future. It perceives that the permissible subjects of patents are as broad as man's technological grasp, and so is written out in broad and forward-looking terms with the aim of extending our reach in every useful direction. Its purpose is not extended, but rather fulfilled, when a new-born technology comes within its purview.

Secondly, the Patent System is, out of necessity, neutral. It cannot be too finely tuned to the kind

(as distinguished from quality) of creation involved, if it is to achieve its task of encouraging the dissemination of what is new and imaginative and useful, so it can be finally judged in the marketplace of ideas and things. Most particularly must it abjure prior restraints, because they chill expression in literature and science alike. The neutrality of the Patent and Trademark Office requires that it leave to other agencies the regulation of technology, after the fact of its creation. Its different job is to inspire creations of every kind, and then before the fact of their creation.

Petitioner's argument from the controversiality of recombinant DNA technology is both misleading and irrelevant. It is misleading because the controversy has largely dissipated. It is irrelevant because controversiality cannot be made the judge of patentability, else the most revolutionary inventions would go unrewarded and the domain of patent law would be relegated to that of gadgeteers alone.

It is Petitioner, not Respondent, that would cast this Court in a legislative role. This Court is ill-equipped to determine when and then to what extent the needs of society require that any given technology be deleted from the broad compass of the patent laws. Congress, on the other hand, has that capability and has exercised it in the past, both prospectively and, as to already issued patents, retrospectively. See 42 U.S.C. 2181(a).

The new biology holds enormous promise in application for the public good. Much tangible benefit is already in hand. Despite the contrary view of Amicus The Peoples Business Commission, it is the job of the Patent System to generate greater momentum in such research and in all research that promises advan-

tage. Regulating the product of research must fall to agencies other than the Patent and Trademark Office, which is itself inept as a regulatory tool. In any event, no regulatory purpose would be served by denying patents on microorganisms while continuing to grant them on processes of creating and using such organisms; while permitting academic research to go forward indifferent to either profit or patents; and while permitting even industrial practitioners to seek trade secret alternatives, so defeating the role of the Patent System as an information clearinghouse.

On the other hand, grant of microorganism patent protection is required to avoid opportunities for cynical evasion of patent laws as they attach to processes alone. Nothing in the legislative history prohibits such patents. Instead, the logic and greater purpose of the Patent System compels them.

Petitioner Is Seeking Judicial Legislation in Policy Areas Unsited to Judicial Consideration, Proceeding From a Premise Wholly at Odds With the Logic of a Patent System.

No one will dispute the notion that patent laws are written to incent the creation of things outside the contemplation of those who enact such laws. Perforce, patent laws are written in large and prospective terms, so as to include "anything under the sun that is made by man".⁴ The genius of the patent system is that it extends and enlarges useful technology. Having been designed to inspire new technology, the system is not itself "extended", but rather fulfilled, when the

⁴*In re Chakrabarty*, 596 F.2d 952, 987 (1979), quoting both House and Senate reports accompanying the 1952 enactment of Title 35, U.S.C.

desired results are attained and new science comes under its protection.

The best science and the best of invention is that properly described as "revolutionary", a term that bespeaks profound and often sudden change in the way men live their lives. A common consequence of revolutionary invention is widespread impact at every level of society. Undue caution in admitting inventions of that character to the protection of patent would, in the end, fashion a result antithetical to that envisioned by Congress. Only the most mundane innovation would be rewarded, and the grant of patents confined to the very "gadgets" reviled by Justice Douglas, concurring in *Great A. & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 156 (1950).

Revolutions in science generate "empirical data" of the sort referred to by Justice Stevens, writing for the Court in *Parker v. Flook*, 437 U.S. 585, 595 (1978), in direct proportion to their impact on society. We agree that such data is grist for the Congressional mill, and ill-suited to assessment by the Supreme Court. For precisely that reason, we submit that if newly created technologies of wide-ranging impact are to be subtracted from the broad compass of patentability, it is Congress that in the first instance should essay that task. To paraphrase the brief of Petitioner.⁵

"Congress, rather than the judiciary, is empowered and is best able to resolve the complex social, economic, and scientific questions frequently involved in such decisions, and, if [a deletion] is to be made, to tailor the statute to achieve precisely the desired ends."

⁵Brief for the Petitioner at 9-10.

Congress has proven its ability to tailor the patent statute in exactly that fashion, as witness 42 U.S.C. 2181(a):

“No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor.”

When that section was enacted atomic research was controversial in all its parts, and it remains so even to the present day. Yet Congress had the facility, as this Court does not, to limit its “tailoring” of the Patent System by the dictates of policy in a complex field, and it exercised it so as to proscribe only certain patents, while permitting such others as those later issued to Glenn Seaborg⁶ for the creation of the isotopes that are Elements 95 and 96 of the Periodic Table.⁷ The surgical precision of Congress’ action in this regard stands in sharp contrast to the meat-ax approach Petitioner now urges. Thus, Petitioner would have the Court proscribe the grant of patents across the full length and breadth of a “vast” field, one whose span includes everything from beer-making to gene-splicing, and then to do so because a *part* of that field is “controversial”.

Endless mischief would result from adoption of Petitioner’s approach to resolving “patent-ability” questions by reference to policies outside those embodied in

⁶U.S. patents 3,156,523 and 3,161,462.

⁷Indeed, it was the Government itself which applied for and obtained those patents, Seaborg being its employee.

⁸Brief of the Petitioner at 20.

the Patent Act itself. Each time there arose a pioneer technology of societal consequence, courts would be asked to constrict the patent laws until Congress could adjust the competing policy considerations involved. The job of Congress would reduce to more or less piecemeal restoration of the Patent System, technology by technology. When each technology was restored by Congress to its rightful place within the broad and forward-looking language of 35 U.S.C. 101, only the efforts of those who created the technology would go unrewarded, for their patents would have in the meantime been denied. Petitioner’s argument from caution in “extending” the patent incentive leads ineluctably to this absurd conclusion.

It is one thing to decry interstitial additions by the judiciary to the patent laws, as does the dissent below.⁹ It is quite another to urge, as does Petitioner, interstitial deletion of whole technologies from the operation of those laws. The latter asks the Court to legislate in the stead of Congress, and then in areas peculiarly unsuited for judicial treatment. Most particularly should the Court eschew such action when Congress has demonstrated, as it did in enacting 42 U.S.C. 2181(a), its refined ability to both adjust the scope of the patent laws and to revoke patents whose interim grant appears to it, in retrospect, to have been improvident from the standpoint of policy.

The Argument From Controversiality Is Misleading.

Both Petitioner and Amicus, the Peoples Business Commission (PBC), refer repeatedly to the “controversial” aspects of genetic engineering, as if controversy

⁹*In re Chakrabarty*, 596 F.2d 952, 1002 (Miller, J., dissenting).

were to be made the judge of patentability. The argument from controversy, we suggest, is both misleading and irrelevant. To begin with, animal cloning, test tube insemination and other extravagances have nothing to do with the minute concerns of Chakrabarty, and those in turn have nothing to do with gene-splicing, which alone has generated all the controversy. Even the concern over recombinant DNA technology has, we think, been greatly overblown in the briefs favoring reversal. Though hotly debated just a few years ago, DNA technology "is now in wide use" and, according to Dr. Walter Gilbert of Harvard University, "worries about the dangers of genetic engineering have all but disappeared".¹⁰ In fact, the Director of the National Institutes of Health has approved the large-scale production of insulin by recombinant DNA organisms.¹¹ In fact, at last count the same Government agency was itself funding fully 717 research projects in the field, to the tune of some 91.5 millions; preliminary studies conducted by the Government have reportedly failed to demonstrate any significant danger associated with recombinant DNA research.¹² Against a backdrop of active promotion of such research by European governments and concern over possible loss of this country's technological lead in the area, a spokesman for Congress' Office of Technology Assessment has suggested

¹⁰As quoted in "'Glamour Stock' Could Help Cancer Patients", *Los Angeles Times*, issue of January 21, 1980, Part I, pp. 3, 16.

¹¹Letter dated December 13, 1979, Elizabeth Milewski, Scientist Administrator, Office of Recombinant DNA Activities to Dennis Kleid, Chairman, Biosafety Committee, Genentech, Inc.

¹²"Where Genetic Engineering Will Change Industry", *Business Week*, October 22, 1979, 160, 164.

that "government's stance may change from regulation to promotion" of the science.¹³ And while Petitioner suggests¹⁴ that it was "continuing controversy" that led the National Institutes of Health to revise its guidelines for research in the area, it was actually the *diminution* of that controversy which led the agency to significantly *relax* those very guidelines.¹⁵

The Argument From Antagonism to Science.

The attempt to cast this Court in a legislative role is nowhere more evident than in the brief amicus of the Peoples Business Commission (PBC), whose essentially Luddite philosophy¹⁶ would have the Court stand the Patent System on its head, denying patents so as to avoid

"... generating a greater momentum in research and development of genetic engineering technologies . . . [which] . . . in turn, will lead to the rapid proliferation of genetic techniques in the areas of energy, agriculture, medicine, industrial processes and many other aspects of the nation's economic life."¹⁷

But the question before the Court is neither one of ethics, nor philosophy, nor politics. It is one of statutory interpretation, of grammar leavened with reason. Despite the invitation of PBC, it is not for this Court

¹³*Id.*, quoting Zsolt Harsanyi.

¹⁴Brief for the Petitioner at 19.

¹⁵Op. cit. supra, n.12.

¹⁶The Luddites of early nineteenth century England sought to prevent the spread of labor-saving machinery by the simple expedient of destroying it. For industrial purposes, bacteria that produce human insulin can be regarded as life-saving machinery.

¹⁷Brief Amicus Curiae of Peoples Business Commission at 3.

to question Congress' wisdom in enacting either the Plant Patent Act¹⁸ or the broader provisions of 35 U.S.C. 101, nor to attempt, like King Canute, to command the tide of technological development.

It is true that genetic engineering is pregnant with potential for altering the human condition. As advances in electronics and plastics led to the implantation of pacemakers and artificial heart valves, so advances in genetics could one day lead, by gene transplants, to the elimination of sickle cell anemia, Tay-Sachs and other genetic diseases. But to suggest, as PBC does, that affirmance of the decision below would bind the Court to construe the Act as permitting patents on all forms of life, even "a human being manufactured to desired specifications"¹⁹ extends literalism beyond reason. One might as well argue that the definition of "meat food products" in 7 U.S.C. 182(3) extends to anthropophagy because it can be literally construed as inclusive of human parts, or that because humans are members of the kingdom Animalia, the Secretary of Agriculture is empowered under the Animal Welfare Act of 1970 "to protect the owners of [humans], from the theft of their [humans],"²⁰ so resurrecting the fugitive slave laws. The patentability of homunculi²¹ is not the issue before the Court, and altruism is misplaced if, on behalf of invisible bacteria that can be freeze-dried to a powder having no semblance of livingness, it argues for the dissuasion of life-giving research.

¹⁸Plant Patent Act of 1930, 35 U.S.C. 161 et seq.

¹⁹Op. cit. supra, n.17, at 25.

²⁰See 7 U.S.C. 2131, 2132(g).

²¹Manikins made in flasks by alchemists.

PBC asserts "the public's right to a diversified gene pool composed of naturally occurring life forms"²². It wants noting that the naturally occurring life forms most likely to be impacted by the flowering of recombinant DNA technology are those no one will miss at all, deadly vectors associated with such horrific diseases as Lassa Fever, the scourge of Southern Africa; Influenza, which in 1918 slew more than died in the Great War; Epstein-Barr virus, which potentiates one form of cancer in blacks, another in Orientals, and causes mononucleosis in Caucasians; rabies; shingles; foot and mouth disease; and endless others. Even cancers could fall across a broad front, if the promise of interferon produced by recombinant microorganisms holds true.²³

At bottom, it is clearly in the public's interest to retain patent incentives for inventions in the life sciences in general, and in recombinant DNA technology in particular. If controls are to be imposed on research in those areas, judicial abandonment of the patent reward is not the way to do it. Congress has proven,

²²Brief Amicus Curiae of Peoples Business Commission at 13. The accompanying argument that patenting microorganisms could diminish the 'diversity of the gene pool' on planet earth can scarcely be credited, when any shovel-full of backyard sod can yield micro-organic life in endless variety, and when genetic engineering itself permits the creation of new varieties, so tending toward greater and more useful diversity.

²³Interferon is produced in the body to stimulate defense mechanisms against cancers and viruses. Small amounts have been conventionally produced in the laboratory at enormous expense, but recombinant DNA technology may yield a cheap and plentiful source of the material. Just weeks after the filing of Petitioner's brief, a precursor form of interferon was reportedly made in that way by altered bacteria. "Scientists Produce Protein in Laboratory," *The Los Angeles Times*, edition of January 17, 1980, Part I, p.28. The achievement was reported by Biogen, S.A. which, like Amicus, is a small venture capital company.

time and again, its ability to devise more suitable means of control, as witness a host of regulatory agencies. The more so should such questions be left to future Congresses where the record so far in hand is overflowing with evidence of the beneficial practice of recombinant DNA technology, yet contains not a single instance of any associated harm.

The Denial of Patents on Microorganisms Would Accomplish No Regulatory Purpose.

It can readily be demonstrated that the denial of patents on microorganisms would serve no public interest at all, let alone those for which Petitioner and PBC contend in particular.

To begin with, denial would not diminish the administrative burden of patent examination one iota. Whether the patent claim is directed to an oil-degrading microorganism itself or, say, to a method of combating oil spills that involves deploying a mixture of organism and straw on a spill, the same issues of novelty, utility and unobviousness must be resolved, and in either case the organism must be described and distinguished from the things that have gone before.

Again, it is idle to speculate that denial of patents on microorganisms would be an effective means of curbing their construction, when everyone agrees that patents can continue to issue on methods of constructing them or, more commonly, methods of using them in industry.

Where the limitations of process patents did discourage patent filings, work at an industrial level would, perchance, go forward anyway. As one commercial practitioner has suggested, "you keep your proprietary

strains under lock and key"²⁴; that is, forever a trade secret. Were this to happen, the only result would be defeat of one principal purpose of the Patent System—to enhance learning through encouraging disclosure of useful information.

And if the diminution of meaningful patent protection did act as a disincentive to industrial exploitation, no corresponding diminution in biohazard, if indeed any exists, would result. That is so because the controversy over hazard has nothing to do with patents. A biohazardous experiment involving bacteria would be as dangerous if practiced at a laboratory bench in academe as when done at large in industry—perhaps more so, through inattention to the economic consequences of carelessness. Academic and industrial hazard in this area, if it exists at all, is at least in parity. A single virulent organism escaping a University laboratory could rival, virtually overnight, a million-fold escape from a factory. The point is that the denial of patents could inhibit only industrial application of the new science, perhaps the most useful kind. Academicians could continue equally "hazardous" experimentation, indifferent to either profit or patents.

Finally, there is the alternative of patents on plasmids themselves. Plasmids in recombinant bacteria are like carburetors in engines. Properly installed, they permit the bacterial engine to cough into useful life, producing the precious substances whose genetic information they encode. But plasmids are absolutely inanimate. Each building block of the plasmid (and plasmids can be built) is an absolutely dead bench chemical. All of

²⁴"Where Genetic Engineering Will Change Industry", *Business Week*, October 22, 1979, 160, 172 (quoting Leslie Glick, of Genex).

the building blocks in the aggregate are little else. The chemical composition of the plasmid they form is absolutely definable. By every imaginable test, the new plasmids that confer near-miraculous properties on everyday organisms ought to be patentable, just like any other man-made chemical of value. And just as someone who makes, uses or sells an automobile containing a patented carburetor can be sued, so too one who makes, uses or sells a bacterium containing a patented plasmid should be subject to suit for infringement.

Two things remain to be said about plasmids.

First, pending the resolution of the *Chakrabarty* matter, the Patent and Trademark Office has suspended the examination of patent applications that claim plasmids²⁶, despite the universal practice in this country of granting patents on inanimate chemical substances and despite the fact that no claim to a plasmid is before this Court. Even an adverse opinion of the Court with regard to the patentability of living things, then, should be careful to preserve the patentability of new but dead chemicals, like plasmids, that meet all the normal criteria of patentability. It is interesting to observe that in the *Chakrabarty* application the Patent and Trademark Office proved quite willing to grant claims directed to the combination of living organisms and straw, presumably for use in combating oil spills. Can it be said that Congress intended patents on living organisms inside inanimate bits of straw but prohibited them in the case of inanimate bits of chemical inside microorganisms, or are we beginning to draw distinctions that border on the silly?

²⁶Private Communication. Examiner A. E. Tannenholtz to the Author, November 13, 1978.

Secondly, the continuing availability of patents on plasmids undercuts the proposal by PBC that this Court's decision be aimed at disincenting the practice of genetic engineering. If plasmids are patentable *in se*, and the Patent and Trademark Office has failed to articulate any reason why they are not, then the practitioners of recombinant DNA technology will be largely unaffected by a ban of patents on microorganisms.²⁶ Ironically, only those in more conventional fermentation industries will suffer because in those, new microorganisms are gotten in other ways, without the creation of new and independently patentable plasmids.

At bottom, the Patent System is an ingenious vehicle for the inspiration of new technologies. It is an inept tool for their regulation and the attempt to surround it with a regulatory aura, because illogical, is deserving of rejection.

Microorganism Protection Is Required if Cynical Evasion of the Patent Laws Is to Be Avoided.

The fear has been widely expressed that the United States increasingly is losing its technological lead, and that the loss of that lead can be expected to severely

²⁶The plasmid question, we add, offers the Court an interesting opportunity to accommodate the interests of both parties in the present matter. *Nothing* in the legislative history of the Patent Act could be construed as proscribing patents on dead chemicals like plasmids. The grant of patents on plasmids could satisfy the needs of a burgeoning and bountiful industry, without reaching the issue of patents on life forms of any kind, let alone higher forms. And although no "plasmid" question is before the Court, the predisposition of the Patent and Trademark Office referred to in the text (which is tied by it directly to the outcome of the present matter) should command both the attention of this Court and care in phrasing its opinion.

impact America's balance of payments and other indicia of economic health. And yet, increasingly, that picture is brightening. According to one commentator:

"[I]n newer industries the level of research is high and American innovation is the envy of the world."²⁷

And, of course, one of the new industries to which the author points is genetic engineering itself. In another article,²⁸ encouragingly entitled "U.S. Innovation: It's Better Than You Think," the authors find increasing evidence that new enterprises, most particularly in "the exciting science of genetic engineering", are behind a resurgence of domestic innovation. The encouragement of domestic innovation is important, and that can best be done by a strengthened patent system, as both Congress and the President have agreed.²⁹ In the important field of genetic engineering, that system would be best strengthened or, for that matter, restored by the grant of patents on microorganisms.

Virtually every one of the most remarkable feats of recombinant DNA technology has involved the creation of a new microorganism. But once a single microorganism has been created, in the culmination of what may have been years of work, the process of creation may need never be repeated because, once made,

²⁷"Innovation—Has America Lost Its Edge", *Newsweek*, June 4, 1979, 58, 59.

²⁸*Dun's Review*, March, 1979, at 55.

²⁹125 Cong. Rec. H22, 912 (daily ed. Feb. 27, 1979); 430 BNA Patent, Trademark & Copyright Journal (BNA); 125 Cong. Rec. 567, 6715 (daily ed. May 24, 1979); Industrial Innovation Coordinating Committee Subcommittee on Patent and Information Policy, Draft Report on Patent Policy §2 (III) (1978); 430 Patent, Trademark & Copyright Journal (BNA) A-2.

the microbe does all the work. It reproduces itself and its new capabilities, time and again. The process can go on indefinitely, certainly throughout the seventeen year term of a patent that may in the meantime have issued.

Absent patent protection on the microorganism itself or, at the least, on its key components,³⁰ numerous opportunities will arise under which others:

"... would then be allowed to reap the fruits of the American economy—technology, labor, materials, etc.—but would not be subject to the responsibilities of the American patent laws."³¹

After disclosure of the invention whose practice creates the organism, but before actual grant of the patent, others could practice the invention *once*, making an organism that would thereafter perpetuate itself without infringing the later-issued patent. Again, even after the process patent had issued, another could repeat the process outside our borders and beyond the reach of the patent. The resulting organism and its progeny could then be freely introduced to the United States, leaving the process patent holder to his remedy, uncertain at best, in proceedings before the International Trade Commission.³² Indeed, in the special circumstances of microbiological patenting, it could become possible for the cynical "infringer" to make no organism at all, but rather to obtain and use the inventor's own microorganism from a culture collection in which it has been deposited to satisfy the disclosure require-

³⁰See text accompanying note 26, *supra*.

³¹*Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 534 (Blackmun, J., in dissent, quoting the opinion of the Fifth Circuit in the same matter, 443 F.2d 936, 939).

³²See 19 U.S.C. 1337, 1337a.

ments of the Patent Act.³³ Here the holder of a patent confined only to the process by which his micro-organism was created must, absent affirmance of the decision below, sit idly by while another uses that very organism to compete with him in producing an end-product that is itself unpatentable because earlier available from other sources. That is so because the law at present prohibits any restriction on third-party use of deposited organisms, once the patent has issued, and instead then leaves the creator of the organism to his infringement remedy.³⁴ Absent claims on the organism itself and in the circumstances described, that remedy may be nonexistent.

The iniquitous evasion of the patent laws that could result can be avoided by confirming in inventors their right to effective patent protection on the products of their often-stupendous labors, even when those products are "alive". And to do so requires no extra-territorial extension of the patent laws, as was sought in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), but rather only that their purposes be effectively implemented *within* our borders.

The Argument From Legislative History.

It should come as no surprise to Petitioner that the decision below is the first holding of its kind in almost 190 years of American patent jurisprudence.³⁵ The question has simply never before come before any court, and under Article III of the Constitution the courts are bound, case-by-case, to resolve only

³³*In re Argoudelis*, 434 F.2d 1390 (CCPA 1970).

³⁴*Feldman v. Aunstrup*, 517 F.2d 1351 (CCPA 1975).

³⁵But see Brief for the Petitioner at 13.

the controversies that parties put before them. Petitioner has accordingly been obliged to mine not any body of judicial precedent, but rather a narrow and, in the view of this Amicus, vanishing vein of legislative history.

We believe that the pertinent legislative history (or, in the present case, essential non-history) of the Patent Act reduces to a small number of common-sense propositions apparent from the brief of Respondent and those of other amici:

First, there is no meaningful evidence suggesting that in enacting 35 U.S.C. 101 and its predecessors Congress thought anything about the patentability of microorganisms, either yea or nay. Instead, it clearly sought by broad language to encompass every *new* and useful process and tangible thing that could meet the criteria, including description criteria, of the general patent laws.

Secondly, Congress enacted the Plant Patent Act³⁶ to broaden the availability of patents, so as to satisfy plant developers otherwise unable to protect their creations because of product of nature and descriptonal difficulties arising under the general patent laws.

Thirdly, the exclusion of bacteria from the Plant Variety Protection Act³⁷ was, pretty clearly, no more than Congressional codification of the decision in *In re Arzberger*, 112 F.2d 834 (CCPA 1940), holding that bacteria were not "plants". That exclusion says nothing contrary to patentability of microorganisms under the general patent laws, in the event they could

³⁶Plant Patent Act of 1930, 35 U.S.C. 161 et seq.

³⁷Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542, 7 U.S.C. 2321 et seq.

conform to utility, novelty, non-obviousness and the more rigid description requirements of those laws.

Suppose that when some Congress had before it the job of enacting or amending the patent laws this testimony had come before it:

"There exists, out in the future, a new science whose application could result in giant strides toward the elimination of disease, and of hunger, and the creation of whole new energy sources. It can be discovered and applied to those ends if the patent laws you enact are broadly drawn so as to encompass, and to incent, acts of invention that will bring the new science into view."

Would there later be any doubt that by the broad language Congress *did* use in 35 U.S.C. 101 it intended to incent the attainment of those very goals? Would there be any doubt that it intended to encompass the new science, even though its workings remained unknown when the law was drawn? And is there any doubt but that Congresses of the past *did* have salutary goals like those in mind every time the patent laws came under their hand?

We urge that the Patent Act be construed so as to sustain its large objectives, the ones clearly intended by Congress. To do so will confirm the patentability of microorganisms and both encourage a beneficent science and ensure that broad and forward-looking incentives remain for those who would pull the next technology, the one now invisible because still down over the horizon of the future, into view and into use.

Conclusion.

For the foregoing reasons, the judgment of the United States Court of Customs and Patent Appeals should be affirmed.

January, 1980.

Respectfully submitted,

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Supreme Court of the United States
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CLERK

IN THE
Supreme Court of the United States
OCTOBER TERM, 1979

No. 79-136

SIDNEY A. DIAMOND, COMMISSIONER
OF PATENTS AND TRADEMARKS,

Petitioner,

v.

ANANDA M. CHAKRABARTY

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEALS

**BRIEF ON BEHALF OF THE AMERICAN
SOCIETY FOR MICROBIOLOGY, AMICUS CURIAE**

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**BRIEF ON BEHALF OF THE AMERICAN
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INTEREST OF AMICUS CURIAE

The American Society for Microbiology (hereinafter Society) is a not-for-profit educational and scientific organization dedicated to the promotion of scientific knowledge of microbiology and related subjects.¹ Founded in 1899 as the Society of American Bacteriologists, the

¹ This brief is filed with the consent of both parties pursuant to Rule 42 of the Supreme Court Rules and original letters of consent accompany this brief.

Society was renamed the American Society For Microbiology in 1960 because of the broadening scope of microbiology.

Today, the Society is the largest single life science organization in the United States with over 30,000 members. It embraces 16 subspecialty divisions and publishes eight scientific journals and numerous books. In addition, the Society conducts educational meetings, seminars and workshops and directs certification activities of the American Board of Medical Laboratory Immunology and of the American Board of Medical Microbiology. It is, in sum, the principal scientific organization for microbiologists in the United States.

Underlying the Society's dedication to the advancement of scientific knowledge is its commitment that science serve the public interest. In order to address scientific matters affecting the public interest, the Society has created a Board of Public and Scientific Affairs. The Board is responsible for developing positions for the Society on public policy issues.

In the area of genetic research, the Board has established a Committee on Molecular, Genetic and Systematic Microbiology with the charge to promote the adoption of sound science policies involving genetic and molecular microbiology as they affect the public interest. Six eminent microbiologists serve on this Committee, and the members are intentionally selected to achieve expertise for the Committee in areas of microbiological genetics, virology and systematic microbiology.

The activities of both the Committee and the Board are subject to governance by the Society's managing bodies, the fifteen member Council Policy Committee (Executive Committee) and the sixty member Council (Board of Directors). The Society's procedure for formulating policy

on scientific matters of public interest is designed to produce policies drafted by a Committee of experts, and monitored and coordinated by a Board responsible for serving the public interest in science.

Having adopted careful procedures for the establishment of its policies, the Society seeks to assure that significant public discussions of microbiological issues are based upon objective data. Topics such as genetic research, for example, involve sophisticated and evolving laboratory techniques that cannot be understood easily by the general public. Such topics, nevertheless, are rightly subject to searching public scrutiny and debate.

The Society has not adopted a policy with respect to the desirability of patenting microorganisms. The Society enters this case to provide basic scientific information concerning the methods by which scientists may now apply sophisticated scientific techniques to make novel microorganisms. It is particularly important for the Court to be aware that the capability of scientists to make new microorganisms through modification of genetic elements encompasses a variety of scientific techniques and that each of these techniques constitutes the deliberate intervention of man to create a novel microorganism.

I

SCIENTISTS ARE ABLE TO MODIFY GENETIC MATERIALS TO DEVELOP NOVEL MICROORGANISMS

The genetic elements of living organisms are subject to modifications which occur in nature in random and uncontrolled ways. Mutations occur in which genetic

molecules are changed as a result of cosmic rays, x-rays, ultraviolet radiation or certain chemicals. Once a mutation has occurred, the offspring of a viable new organism may exhibit the new characteristic.

Scientists have long sought techniques for controlling alterations in genetic makeup so that novel organisms may benefit mankind. Indeed, the deliberate alteration of organisms through the application of scientific knowledge is not new. Hybrids of animals and plants are created by combining donor genes to make new species. Creation of hybrids, however, has been limited to species in which fertilization or grafting techniques could be applied.

Recently, scientists have developed techniques for deliberately altering basic genetic makeup to achieve desired characteristics. Such altered genetic elements may be artificially inserted by scientists into a microorganism with the result that the recipient microorganism takes on new characteristics that it would not naturally have possessed. These characteristics then become reproduced in the normal reproduction of the microorganism.

This intentional alteration of genes to achieve a desired microorganism utilizes certain extraordinary properties of deoxyribonucleic acid (DNA). All organisms that reproduce possess a coding of information necessary for their growth and multiplication. Such coding is on chromosomes which are long filaments of DNA which is a spiral molecule in the shape of a twisted double helix.

Strands of DNA are divided into many genes which are the basic unit of inherited information for the organism. Most experiments altering the function of an organism through modification of DNA have been conducted upon single cell microorganisms. In addition to DNA in a chromosome, microorganisms may contain smaller, extrachromosomal pieces of DNA known as plasmids. Regardless of whether a

gene is in a chromosome or a plasmid, each gene is responsible for production of a specific protein thereby directing a specific function of the microorganism.

Techniques developed for altering the genetic makeup of microorganisms by introducing foreign genes are varied. Plasmids and viruses² habitually present in one species of microorganism, where they code for production of a particular protein, may be artificially introduced into another microorganism that normally does not carry out the same biochemical activity. The recipient strain becomes endowed with the new property and the new microorganism may be more useful than previously existing strains. Such procedure requires the scientist to identify microorganisms displaying a desired characteristic, isolate the plasmid containing the gene responsible for the characteristic, introduce the plasmid into the recipient microorganism and achieve compatibility and acceptability for the plasmid within the then new microorganism. Each of these steps involves the planning and execution of sophisticated techniques to achieve a microorganism exhibiting a desired characteristic that has not been found in nature. It was this technique that was used to produce the *Pseudomonas* strain in issue here.

Other techniques are also available. Recombinant DNA technology consists of alteration of a plasmid prior to its insertion into a microorganism. Utilizing recombinant DNA technology, genes from any source may be introduced into a microorganism in order to create a strain exhibiting new characteristics.

In recombinant technology, the scientist isolates a plasmid and, using specific chemicals (restriction enzymes) cuts the plasmid at specific sites. The desired piece of genetic

²Viruses may be used for the techniques discussed herein. This brief will use only the term plasmids.

material is then inserted between the cut ends of the plasmid and the recombined molecule is assembled into the plasmid's characteristic circular form.

Once recombined, the plasmid can be introduced into a suitable recipient microorganism. That organism then becomes endowed with the new gene and hence a new characteristic because the protein dictated by the gene will be manufactured by that microorganism.

Of each of these steps by the scientist - isolation of the plasmid, cutting it, isolation of foreign DNA, insertion of the foreign DNA, fusion of the plasmid, selection of a suitable recipient and actual insertion - the most technically demanding is the isolation of specific foreign DNA.³ This can be done either by the actual chemical synthesis of a gene or by the identification and purification of the gene from another organism.

To synthesize the gene, a scientist identifies the protein to be manufactured at the direction of the gene and determines the sequence of amino acids forming that protein. Knowing the genetic code — the relationship between particular amino acids and the structure of the gene itself — the scientist may then synthesize DNA that corresponds to the proper protein. Essentially, therefore, the scientist makes the gene that is then inserted into the severed plasmid and recombined for artificial introduction into a microorganism.

Alternatively, the scientist utilizes a trial and error method, cutting and recutting chromosomes to identify that portion of the chromosome - the particular gene - causing production of the protein. Once determined, the gene is

³To illustrate the difficulty, *E. Coli*, a standard colon bacillus, contains over 3000 genes that are chemically similar. Isolation of a gene directing a specific function may require years of work and millions of dollars.

isolated and, by the techniques described above, is introduced into a suitable recipient.

Regardless of whether recombinant DNA or other techniques are used, the scientist not only determines what gene reproduces a particular characteristic, but also chooses a recipient microorganism, identifies and isolates plasmids or genes for insertion and makes the insertion through sophisticated techniques. Success in making a new microorganism also depends upon the success of the scientist in purifying a strain, maintaining its stability with the plasmid and causing it to manufacture protein and reproduce itself. The result is a new microorganism which has not been found in nature and which has been deliberately designed and laboriously made for the benefit of man.

II

THE MANUFACTURE OF NOVEL MICROORGANISMS PROVIDES IMPORTANT BENEFITS FOR THE PUBLIC AND FOR THE EXCHANGE OF SCIENTIFIC INFORMATION

Although the benefits of application of genetic research techniques are not an issue in this case, the parties and *amici* agree that the patentability of microorganisms will affect the pace of genetic research and the exchange of scientific information. The Society, therefore, cannot simply ignore such benefits. Present and potential benefits to the public and to science are multifarious and significant. Even a condensed review of benefits suffices to place the capability of science to make new microorganisms in a rational context. Further, the Court should be aware of a specific benefit

patentability would provide for the exchange of scientific information.

A. Benefits to the Public

Utilizing the described processes, scientists are now able to produce valuable human proteins. Human hormones may be yielded in formerly unavailable quantities thereby significantly improving therapy for certain medical conditions.

For example, recombinant DNA technology has already resulted in the bacterial production of somatostatin, a hormone naturally produced in the brain. Somatostatin is important in the treatment of acromegaly—a form of gigantism—and also in the treatment of certain forms of diabetes. Through use of a new bacteria strain with a gene inserted for the expression of somatostatin, the quantity of somatostatin produced from 100 gms. of bacteria in 2 gallons of culture medium is equal to the amount previously extracted from 500,000 sheep brains.

Additionally, the possible isolation of the insulin gene and the recent announcement (*Washington Post*, Section A, page 7, Col. 1, January 17, 1980), of inducement of microorganisms to produce a duplicate of interferon⁴ are important developments.

The long range benefits are even more impressive. Genetic research and application of the knowledge will lead to a fuller understanding of genetic mechanisms. Knowledge of such processes may lead to anticipating and preventing genetic disorders and diseases and to altering the genetic

⁴Interferon is a substance produced in small quantities within humans. It has been demonstrated to be effective in attacking certain viruses and may prove to be exceedingly important in fighting virus diseases. Further, it has shown some preliminary benefits in attacking cancer.

structure of plants to increase food production.

Application of this knowledge to the symbiotic nitrogen fixation between root nodule bacteria and leguminous host plants may lead to a broader range of hosts, ultimately increasing the capability for nitrogen fixation among cereal plants. Higher crop yields at substantially lower cost would be the beneficial result of such advances.

Scientists will also learn a great deal more about mechanisms of cellular differentiation whereby some of the cells of the body form skin, others form muscle or skeletal tissue, and still others aggregate to form highly specialized organs, such as the heart, lungs, spleen, pancreas, etc. Such knowledge will be useful in controlling mechanisms whereby normal cells become transformed into cancerous cells, whereby some individuals and some tissues are more susceptible to disease than others, and whereby some diseases of genetic nature are passed from parent to offspring.

B. Benefit to the Exchange of Scientific Information.

Patenting of microorganisms is likely to enhance the exchange of scientific information because patent applications must be supported by a description which permits others to reproduce, to improve and to expand upon the patented item. 35 U.S.C. § 112. Microorganisms, however, cannot be produced easily based upon a written document and, consequently, may not be placed in the hands of other researchers by written description in a patent application.

For this reason, the United States Court of Customs and Patent Appeals has mandated that a prospective patent holder for a process of making a microorganism must deposit

a new microorganism in a recognized national culture depository before filing a patent application. *In re Argoudelis*, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970) (United States application); *Feldman v. Aunstrup*, 517 F.2d 1351, 186 USPQ 108 (CCPA 1975) (International application)⁵ The applicant must identify the depository where the microorganism culture is deposited, give the depository's accession number and provide a description of the microorganism — for example, its morphological characteristics.

In addition, under *Argoudelis* and *Aunstrup*, the applicant's agreement with the depository must provide that the microorganism will be made available to responsible persons by the depository upon the granting of the patent. Thus, upon the grant of a patent involving a new microorganism, researchers are able to obtain a sub-culture of the microorganism from the depository without payment of royalty or license fee to the patent holder.⁶

The availability of a subculture is especially important for scientific research, because actual strains are needed for experiments. Yet, it is unlikely that commercial firms will deposit newly discovered microorganism cultures in a

⁵Although these cases involve process claims, the requirement of placement in a depository would be equally applicable to claims upon an organism itself. Indeed, it should be noted that the techniques for applying genetic research will eventually become increasingly well known and process claims will, with greater frequency, be found unpatentable because they will be "obvious". *In re Larsen*, 292 F.2d 531, 130 USPOQ 209 (CCPA 1961). Thus, patenting of the microorganism itself will likely be more important than patenting of the process. See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

⁶A license from the patent holder will be required if the microorganism is made, used or sold in a commercial sense, but not for the sole purpose of testing or conducting research with the microorganism.

recognized depository if adequate patent protection is unavailable. The absence of patenting, therefore, would preclude acquisition of strains by researchers and would inhibit the exchange of information that is vital to research.

As an example of the operation of the deposit system, cultures of the *Pseudomonas* strains at issue in this case are on deposit with the United States Department of Agriculture Northern Regional Laboratories. If the patent application is upheld, any researcher will be entitled to a subculture for use for experimental purposes. Thus, this case presents an illustration of the benefits likely to flow to genetic research from patenting.

CONCLUSION

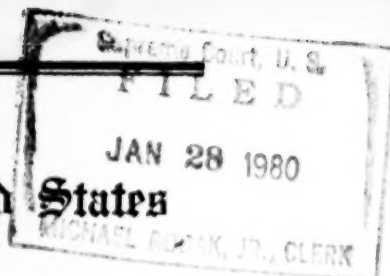
Insertion of genes into selected microorganisms creates novel microorganisms which have not been found in nature. These techniques and the microorganisms made by them hold promise for many beneficial uses for man.

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IN THE
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vs.

ANANDA M. CHAKRABARTY,

Respondent.

**BRIEF ON BEHALF OF THE NEW YORK PATENT LAW
ASSOCIATION, INC. *AMICUS CURIAE***

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ASSOCIATION, INC. *AMICUS CURIAE***

Question Presented

Is the invention of an industrially useful, man-made microorganism excluded from patent protection as a "manufacture" or "composition of matter" under 35 U.S.C. §101 because the microorganism is alive?

Identity of Amicus

The New York Patent Law Association, Inc., is an association comprised of over one thousand private and corporate attorneys who practice patent and trademark law in the New York metropolitan area. Our association is concerned with the advancement of the arts and sciences through an effective patent system. Apart from this general public interest, we have no interest in the outcome of this proceeding. The consent of the parties to the filing of this brief has been obtained and is being separately filed with this Court.

Summary of Argument

For purposes of this brief, we accept the petitioner's statement of the case. Petitioner's statement of the question is too broad for the reasons given by the court below; accordingly we adopt the lower court's statement (596 F.2d at pp. 975-6) paraphrased as set forth above.

Petitioner's brief begs the question by arguing that the Patent Act should not be "extended" to cover new life forms. No such extension is involved here. Rather, the lower court on two separate occasions has carefully considered and concluded that the language of 35 U.S.C. §101 already permits issuance of a patent on "any . . . new and useful . . . manufacture, or composition of matter" and thereby comprehends the invention concededly¹ made by respondent herein.

¹ The novelty and utility of the invention and the adequacy of the disclosure and claims directed to that invention (covered by 35 U.S.C. §§102, 103 and 112 respectively) are admitted by peti-

(Footnote continued on following page)

In doing so, the lower court followed the statutory approach set forth by this Court in *Fortnightly Corp. v. United Artists*, 392 U.S. 390, 396 (1968):

. . . our inquiry cannot be limited to ordinary meaning and legislative history, for this is a statute that was drafted long before the development of the electronic phenomena with which we deal here. In 1909 radio itself was in its infancy, and television had not been invented. We must read the statutory language of 60 years ago in the light of drastic technological change.

In *Fortnightly* and more recently in *Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 158 (1975) this Court cited with approval the following holding in *Jerome H. Remick & Co. v. American Automobile Accessories Co.*, 5 F.2d 411 (6th Cir. 1925):

While the fact that the radio was not developed at the time the Copyright Act . . . was enacted may raise some question as to whether it properly comes within the purview of the statute, it is not by that fact alone excluded from the statute. In other words, the statute *may be applied to new situations not anticipated by Congress*, if, fairly construed, such situations come within its intent and meaning . . . While statutes should not be stretched to apply to new situations not fairly within their scope, *they*

(Footnote continued from preceding page)

tioner. Process claims to the invention stand allowed. The only issue (Ref. petitioner's question) is whether 35 U.S.C. §101 bars a patent on the *product*. Hence, this Court should avoid "importing into its inquiry under 35 U.S.C. §101 the criteria of novelty and inventiveness. Section 101 is concerned only with *subject-matter* patentability." (emphasis added) *Parker v. Flook*, 437 U.S. 584, 600 (1978).

should not be so narrowly construed as to permit their evasion because of changing habits due to new inventions and discoveries. (emphasis added).

Approached from this viewpoint, the statutory language "any . . . new and useful . . . manufacture, or composition of matter" does not preclude but instead broadly comprehends issuance of patents on animate as well as inanimate inventions that are manufactures and compositions. Animate and inanimate inventions may be patented so long as they satisfy the other "conditions and requirements" (35 U.S.C. §101) of the Act and thereby "promote the Progress of Science and useful Arts". U.S. Const. art. 1, §8.

It makes no sense for petitioner to argue that an emerging field of technology is unpatentable because it broaches "areas wholly unforeseen by Congress". The underlying philosophy of the Patent Act is that disclosures of new technology so benefit the public that they should be encouraged. The more revolutionary the technology, the more its disclosure promotes the progress of the useful arts. It is therefore a logical absurdity to suggest that Congress intended some technology to be outside the scope of the Patent Act solely because it was "too new"—too radical a departure from what had gone before.

We recognize that the Chakrabarty invention stands at the cutting edge of biological technology—nothing less than a new microorganism which never existed until synthetically created by its inventors. Regardless of the outcome of this case, research in this new field will proceed at an ever-increasing pace. The question this Court must face is whether that research will continue only under the cloak of trade secrecy or under the full disclosure requirements of the patent system. Beyond any doubt, the patent

approach better meets the Constitutional purpose of promoting the progress of science and useful arts.

Contrary to the petitioner's argument, the issue is not whether research into living microorganisms and genetic engineering raises serious economic and social questions and thus should be regulated. The Patent Act says nothing which even remotely suggests a relationship between patentability and the economic or social sensitivity of given fields of research. Nobel's research on dynamite had dramatic social and economic consequences, as did Fermi's work with nuclear fission, but this had no bearing on the patentability of their inventions and discoveries. Totalitarian states exile their out-of-step scientists. A free society demands that its scientists not be discriminated against, even discrimination through denial of patents on their work because in the view of some people their work might have serious social or economic consequences.²

Nor is this an issue of obtaining a "monopoly" over new forms of life, as argued by the petitioner. In this time when our nation needs technological innovation, the monopoly argument should be recognized for what it is, i.e., an unreasoned contradiction of the basic purpose of our patent system. The rationale of Mr. Justice Story in

² Of course, this is not to say that research cannot or should not be discouraged, encouraged or otherwise regulated dependent on Congress' determination of the public interest. On the contrary, there is ample precedent for Congress to restrict the normal operation of the patent process when the consequences of a given type of innovation so warrant. For example the Atomic Energy Commission Act (42 U.S.C. §2181) in effect provides for eminent domain taking of patent rights in certain areas of nuclear research. Similarly, in areas sensitive to national security patents may be held in secret (35 U.S.C. §§181-183). However, in all such instances the inventor is ultimately accorded his patent rights or otherwise compensated for them.

Blanchard v. Sprague, 3 Sumner, 535, Federal Cases, No. 1518 (CC Mass. 1839)³ should not be ignored:

... Patents for inventions are ... a just reward to ingenious men, and ... highly beneficial to the public, not only by holding out suitable encouragements to genius and talents and enterprise, but as ultimately securing to the whole community great advantages from the free communication of secrets and processes and machinery, which may be most important to all the great interests of society,—to agriculture, to commerce, and to manufactures, as well as to the cause of science and art. In America this liberal view of the subject has always been taken, and indeed it is a natural, if not a necessary result from the very language and intent of the power given to Congress by the Constitution on this subject. Congress (says the Constitution) shall have the power to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right of their respective writings and discoveries. Patents, then, are clearly entitled to a liberal construction, since they are not granted as restrictions upon the rights

³ Cited with approval by this Court in *Wilson v. Rosseau et al.*, 4 How. 646, 708, 11 L.Ed. 1141, 1169 (1846); *Hogg et al. v. Emerson*, 6 How. 437, 486, 12 L.Ed. 505, 526 (1848); *O'Reilly et al. v. Morse et al.*, 15 How. 62, 118, 14 L.Ed. 601, 625 (1853); *Brooks et al. v. Fiske, et al.*, 15 How. 211, 224, 14 L.Ed. 665, 670 (1853); and *Winans v. Demmead*, 15 How. 330, 341, 14 L.Ed. 717, 722 (1853).

of the community, but are granted to promote science and useful arts.⁴

The decline in America's inventive output corresponds directly with the erosion of our inventors' patent rights.⁵ It thus ill serves the judicious resolution of this issue for petitioner to raise the ludicrous specter of "human life ... 'owned' by patent holders."⁶

Nor is there merit in petitioner's argument that the Plant Patent Act of 1930 somehow changes the meaning

⁴ Mr. Justice Clark in *Graham v. John Deere Co.*, 383 U.S. 1, 8 (1966) characterized the change of attitude of Thomas Jefferson (who drafted the words of §101 here in question) as, "His views ripened ... " in a shift from opposing to favoring the limited monopoly grant. In Jefferson's words, "Certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. ... Nobody wishes more than I do that ingenuity should receive a liberal encouragement." (ibid)

⁵ The contrast between the patent system of the United States as now practiced and competitive foreign systems is drawn by Mr. Irving S. Shapiro, Chairman, E.I. duPont de Nemours & Co., in "Technology's Decline," *Vital Speeches of the Day*, Vol. XLV, No. 12, April, 1979. Mr. Shapiro traces the U.S. decline in innovation to the loss of the patent incentive. He compares the systems of the United Kingdom, West Germany and Japan where "patents tend to be honored" to our system where attitudes and procedures "cast a cloud over patents."

⁶ The mischief of petitioner's position also becomes apparent when one considers the imprecision of the demarcation between things alive and things not alive. Yeast, yogurt, apple cider—apple jack—apple vinegar, et al are "alive". Should this fact alone preclude issuance of a patent to an inventor of a new and useful form or an improvement of these materials? Should the patent issue on condition that the inventor "kill" the organism, thereby destroying its utility? The demarcation between plant (which petitioner concedes is patentable) and animal is even more difficult, further demonstrating the illogic and practical untenability of petitioner's position.

of Jefferson's words enacted in the prior Patent Act back in 1793. On the contrary, Section 101 must be taken as this Court said in *Fortnightly*, supra, 392 U.S. at 401-2, "as we find it". The Plant Patent Act cannot retrospectively constrict the scope of patentable invention contemplated by the clear words of the prior statute ("any . . . manufacture, or composition"). And even if the Plant Patent Act were considered, for reasons discussed by the lower court, it is not inconsistent with but rather agrees with the conclusion that Section 101 was intended to and does comprehend the invention here involved.

ARGUMENT

I.

Contrary to petitioner's argument, the lower court did not "extend" the Patent Act to cover all sorts of new life forms. Rather it correctly found that a new, industrially useful, man-made microorganism should not be denied patent protection as a "manufacture" or "composition of matter" under 35 U.S.C. §101 of the Act.

Petitioner's primary argument is that the Court of Customs and Patent Appeals erred because it extended the coverage of the Patent Act without a clear and certain signal from Congress to new life forms not presently comprehended by the Act. In so arguing, petitioner begs the question.

The lower court made clear at 596 F.2d 984-7 that it was not extending the Act. Rather, the court applied the Act to specific facts which demonstrated that the invention fell within *existing* subject matter patentability requirements of Section 101 of the Act. The lower court

pointed out that the Patent and Trademark Office has from at least as early as 1873 granted patents on living things, the case there being a patent to Louis Pasteur for yeast as an article of manufacture. Also noted were various forms of bacteria, mushroom, virus, plant seeds, eggs—the list was not intended to be all-inclusive but merely illustrative of patents already issued on animate things.

The lower court also cited the House and Senate Reports accompanying the 1952 reenactment of Section 101 which state, "a machine, or a manufacture . . . may include anything under the sun that is made by man . . .",⁷ concluding:

We look at the facts and see things that do not exist in nature and that are man-made, clearly fitting into the plain terms 'manufacture' and 'compositions of matter.' We look at the statute and, plainly, it appears to include them. We look at its legislative history and are confirmed in that belief. We consider what the patent statutes are intended to accomplish and the Constitutional authorization, and it appears to us that protecting these inventions, in the form claimed, by patents will promote progress in very useful arts. When we merely determine the policy underlying a statute we are not making policy. (596 F.2d at p. 987).

⁷ This view is consistent with the above expressed thoughts of Jefferson and Story, and also of Chief Justice Taney in *O'Reilly, et al. v. Morse, et al.*, 15 How. 62, 119 (1853),

Whoever discovers that a certain useful result will be produced, in any art, machine, manufacture or composition of matter, by the use of certain means, is entitled to a patent for it; provided he specifies the means he uses in a manner so full and exact, that anyone skilled in the science to which it appertains, can, by using the means he specifies, without any addition to or subtraction from them, produce precisely the result he describes. (emphasis added).

Petitioner argues that the "only judicial pronouncements on the subject suggested that living things are not themselves patentable" and that the "CCPA had itself so indicated," citing *Guaranty Trust Company v. Union Solvents Corporation*, 54 F.2d 400, aff'd, 61 F.2d 1041 (3rd Cir. 1932), cert. denied, 288 U.S. 614 (1933) and *Application of Mancy, et al.*, 499 F.2d 1289, 1294 (CCPA 1974). There is no basis for petitioner's position that these cases negate patentability herein. On the contrary, the lower court discusses them at 596 F.2d 975-7 and concludes by pointing out:

These decisions illustrate . . . that processes, one of the categories of subject matter specified in §101, are uniformly and consistently considered to be statutory subject matter notwithstanding the employment therein of living organisms and their life processes. Witness the action of the PTO in the present case in allowing the process claims. . . .⁸ (emphasis added)

Having begged the question and assumed, contrary to the fact, that the lower Court somehow "extended" the coverage of the Patent Act,⁹ petitioner argues that this

⁸ The lower court also points out the obvious illogic of the petitioner's position in that petitioner concedes patentability of the life forms here involved when incorporated in a process, but denies patentability when used as a product. The social and economic consequences so troubling to petitioner are no more or less ameliorated by patenting the life forms as process claims rather than product claims. Hence, what impact does the alleged life/non-life distinction have?

⁹ Petitioner also relies on various positions taken by various patent law associations on proposed legislation on what can best be described as peripherally related issues. This argument has so little weight as to warrant little or no response. Viewed in the proper light, it only demonstrates a possibly unduly precautionary attitude on the part of the Bar to ensure application of the law consistent herewith and/or requests for added protection as to plant and animal breeders, such as is discussed by the lower court at 596 F.2d 980-984.

"extension" is improper because there has been no "clear and certain signal" from Congress justifying the extension, citing *Parker v. Flook*, 437 U.S. 584, 596 (1987).

The *Flook* decision does not really bear on the issue at hand. It dealt only with the question of whether a mathematical principle (long acknowledged to be unpatentable) became patentable subject matter under Section 101 upon being tied to a specific application.¹⁰ *Flook* had nothing to do with defining what constitutes a "manufacture" or "composition" under Section 101. Thus, grant of a patent in *Flook* would have constituted an extension of the Patent Act. The present case does not.

Likewise, petitioner's reliance on *Deepsouth Packing Co. v. Laitram*, 406 U.S. 528 (1976) is misplaced. *Deepsouth* involved the use of an issued patent to obtain extra-territorial relief beyond that which the courts had previously granted. Thus, the relief therein sought would have "extended" the patent beyond the geographic scope contemplated by the Act with no supporting signal from Congress. No such extension of rights is involved in these proceedings.¹¹

Petitioner stretches its "clear and certain signal"¹² argument further by arguing in Point II that the Plant

¹⁰ As this Court held, "Very simply, our holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under Section 101." (447 U.S. at 595)

¹¹ The lower court distinguished these cases at 596 F.2d 964-7. Petitioner makes no effort to respond to the distinctions drawn by the court.

¹² The lower court took as its "clear and certain signal" this Court's holding in *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933), "We should not read into the patent laws limitations and conditions which the Legislature has not expressed."

Patent Act in 1930 shows that Congress in 1793 did not intend to protect animate inventions as patentable subject matter. The court below fully answered this argument at 596 F.2d 978-984. Little would be served in repeating or paraphrasing that answer. Instead we would refer only to petitioner's attempted reply.

Petitioner argues first that the views of the 1930 Congress¹³ are "particularly useful" because they "illuminate the meaning of the obscure but key words 'manufacture or composition of matter'" (Pet. Brf. p. 8). Petitioner omits the word "any" which precedes the words "manufacture or composition of matter" in Section 101.

But what is obscure about these words? The word "any" requires no further definition—it is clear on its face. As this Court held in *Gordon v. Appeal Tax Court, Md.*, 44 U.S. 133, 147 (1845), there can be no limiting "refinement upon the etymology of the word 'any,' out of or beyond its meaning in common discourse . . .". What petitioner seeks to do is not only to disregard it (see above), but to inject the opposite meaning of the word into the statute. This was criticized by this Court in *United States v. Noce*, 268 U.S. 613, 619 (1924) as,

. . . a strained method of first finding an inconsistency, by no means clear, if it exists at all, and then erecting it into an implied repeal. Implied repeals are not favored.

The word "manufacture" has been defined in an unrelated but nevertheless valid context as follows:

The word 'manufacture finds its etymological source in the Latin ablative 'manu', meaning 'by

¹³ Petitioner also relies on the Plant Variety Protection Act of 1970. The remarks herein apply to petitioner's arguments on the 1970 Act as well.

hand', and 'facere' meaning 'to make'; hence, 'to make by hand.' It is apparent that this literal definition passed with the coming of the machine age and hence is too narrow for present use. As a result, even the standard dictionaries broaden the scope of its meaning.

In general, there appear to be three essential elements involved in manufacture: (1) original material, referred to as raw material; (2) a process whereby the raw material is changed; and (3) a resulting product which, by reason of being subjected to the processing, is different from the original raw material. *Binswanger Glass Company v. United States*, 293 F.Supp. 676, 679 (D.C. Va. 1968).

The word "composition of matter" has been defined in a patent context as follows:

This phrase covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids. See Walker on Patents, vol. 1, p. 55, par. 14. *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.C. D.C. 1957).

Hence, there is nothing "obscure" about these words. One need not review reams of reports to reveal their meaning. Given their ordinary meaning and viewed in the context of their Constitutional purpose, as was done by the lower court, they clearly comprehend the invention here involved.¹⁴

¹⁴ Petitioner also chides the lower court for not citing more legislative history on Section 101 (Pet. Brf. 9). Since this provision to the extent herein relevant goes back to Thomas Jefferson in 1793, the paucity of legislative history might be excusable.

In further reply to the lower court, petitioner concedes that the court considered the legislative history of the Plant Patent Act and "offered two principal arguments in an effort to explain it away" (Pet. Brf. p. 9). The first of these two "principal arguments" as reported by petitioner was that "Congress did not think it important that plants were alive, but only that they were within an agricultural (non industrial) 'field of endeavor' that required stimulation from the patent system." This is a grossly distorted characterization of the lower court's discussion of the purposes of the Plant Patent Act at 596 F.2d 980-4, as is clear from even a cursory review of this part of its decision.¹⁵

A second lower court "argument" allegedly disposed of by petitioner is that ". . . in 1930, Congress considered that plants were not patentable because they were thought to be a product of nature 'unaffected by the hand of man'". Again, petitioner misses the point of the lower court's decision. Here, the court pointed out that a "secondary purpose" of the Act was "to avoid the *judicial interpretation* . . . that products of nature are not statutory subject matter." (emphasis added). The lower court noted that Congress was aware of this objection and concluded that it would be inapplicable to asexually produced plants because, *inter alia*,

a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor

¹⁵ The *In re LeGrice*, 301 F.2d 929, 939 (CCPA 1962) decision relied on by petitioner supports rather than conflicts with the lower court's decision. There, the court in 1962 noted that, "Current studies to 'break the chromosome code' may" add to our knowledge to the extent that one "may someday secure possession of a plant invention by a description . . . as is now possible in other fields of inventive effort". That day has arrived in this case as to respondent's microorganism.

can it be reproduced by nature unaided by man. . . . (596 F.2d at p. 982-3).

Hence, the lower court's conclusion that the 1930 Plant Patent Act does not relate to the patentability *vel non* of living things is supported by its legislative history. That Act, which was intended to facilitate issuance of plant patents, should not be used to correspondingly obstruct issuance of other patents. And its legislative history should not be used to frustrate the broad Constitutional purpose implicit in the language of Section 101 of the Act that dates back to 1793, i.e., to promote the progress of science and useful arts through the grant of patents to all new and useful manufactures and compositions which otherwise meet the conditions and requirements of the Patent Act.

The lower court's decision is consistent with that purpose.

CONCLUSION

**For the reasons set forth above, the judgment of the
Court of Customs and Patent Appeals should be affirmed.**

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IN THE
Supreme Court of the United States

No. 79-136

SIDNEY A. DIAMOND,
COMMISSIONER OF PATENTS AND TRADEMARKS,
Petitioner

v.

ANANDA M. CHAKRABARTY,
Respondent

**On Writ of Certiorari to the United States
Court of Customs and Patent Appeals**

**BRIEF AMICUS CURIAE OF
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA**

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IN THE
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No. 79-136

SIDNEY A. DIAMOND,
COMMISSIONER OF PATENTS AND TRADEMARKS,
Petitioner

v.

ANANDA M. CHAKRABARTY,
Respondent

On Writ of Certiorari to the United States
Court of Customs and Patent Appeals

BRIEF AMICUS CURIAE OF
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

This brief is filed pursuant to written consent of all the parties. Copies of the consent letters are concurrently being lodged with the Clerk.

INTEREST OF THE AMICUS CURIAE

The University of California is an institution of higher learning, established by the State of California, governed by the corporation, the Regents of the University of California (California Constitution, Art. IX, Sec. 9).

The University operates nine campuses, as well as a number of research centers, both within and outside the State of California. As a part of its educational and related activities, the University sponsors research in many fields of endeavor, including various aspects of microbiology. The University is the primary research instrumentality established by the state under the master plan for higher education for the State of California (Cal. Education Code, § 66500). The University is active in obtaining patents on inventions made in the course of its research. These patents are licensed to industry, and the proceeds after deduction of the cost of obtaining such patents are divided between the inventor and the University. The University uses its portion to sponsor further research.

Inventions arising from the University's own research, which are the subject of pending patent applications, are analogous in many respects to the Chakrabarty invention before the Court. Thus, the Chakrabarty invention involved the selection of a variety of "hereditary units" called "plasmids" (P. Br. 6)¹ from various different individual known bacteria, each having the capability to degrade only individual crude oil components, and the insertion of these plasmids into a single host cell to form a new microorganism in which all of the plasmids for the first time cooperate to metabolize spilled oil.

Relevant inventions made at the University likewise entail the insertion of man-made plasmids containing genes from other organisms into a host microorganism. For example, the University's inventions involve the preparation and insertion into a strain of *E. coli* of plasmids containing mammalian genes which express various proteins such as insulin and growth hormone, in great demand for therapeutic purposes.

¹ See P. Br. 6, including footnote 3.

Whether the University has the right to patent its own newly manufactured microorganisms will depend directly on the disposition that is made in this case.² In turn, this will govern whether the University receives income from these inventions, to be significantly shared with its inventors and to use, *inter alia*, in supporting new research. Indeed, if no patents issue, the health care industry may well elect not to commercialize these important inventions because of its avowed belief that absent the protection a patent affords, the time and experimental work requisite to obtaining government clearances cannot be justified.

STATEMENT OF THE CASE

An appropriate Statement of the Case appears in the brief of the parties.

² Pending the decision in this case, the Patent Office has suspended all action on the University's current patent applications, not only as to the claims for microorganisms *per se*, but also for related subject matter such as "vectors," i.e., chemical compounds, which are not "living".

A typical December 11, 1978 statement of the Patent Office position is

This application contains claims drawn to a cloning vector (e.g., a plasmid) and a microorganism *per se*.

Since the claimed subject matter may be affected by the decisions in the Bergy, et al. . . . and Chakrabarty . . . applications currently before the Court of Customs and Patent Appeals, *action in this case is suspended until final adjudication of those cases.*

Applicants should call this case to the Examiner's attention if they have not received any action within 6 months. (Emphasis by the Patent Office.)

On November 23, 1979, the Patent Office rejected a request for "action on the merits" of only those claims not drawn to a microorganism, *inter alia*, because "the claims to 'a plasmid' and 'a vector' [both nonliving chemical compounds] are considered to be drawn to subject matter that may be affected by the Supreme Court decision."

SUMMARY OF ARGUMENT

The narrow issue solely presented for adjudication is not whether all "living organisms" are patentable, but whether the new and useful microorganism which respondent created by inserting man-made plasmids into a host cell is a "manufacture" under 35 U.S.C. § 101.

As this Court held in *American Fruit Growers, Inc. v. Brogdex*, 283 U.S. 1, 11 (1931), the word "manufacture" in the statute, given its ordinary meaning, contemplates "transformation; a new and different article must emerge 'having a distinct name, character or use.'"

Petitioner's microorganism satisfies these criteria. Hence, the Court's "duty" as defined in *Parker v. Flook*, 437 U.S. 584, 596 (1978) to "construe the patent statutes as they now read in light of our prior precedents" requires affirmance without reference to any legislative history.

Petitioner's excursion into a synthetic legislative history is unwarranted and misdirected. The practical application of the existing patent laws largely excluded "life forms" not because they were alive—a factor not mentioned by the Congress—but because they were either "products of nature" and hence not "new" (R.S. 4886; 35 U.S.C. § 101) or because the statutory requirements for a detailed written description and for precise claiming (R.S. 4888; 35 U.S.C. § 112) could not be satisfied, *inter alia*, because such inventions did not reproduce true to form, i.e., were not "stable".

Because the petitioner, with approbation of the lower court, has already accommodated the description requirements of § 112 to the exigencies of microbiological technology (see *Application of Argoudelis*, 434 F.2d 1390 (1970)), no statutory impediment to the patenting of manufactured microorganisms remains.

This Court should not be distracted from these basic principles which augur strongly for affirmance by the CCPA's specious legal reasoning which seemingly seeks to induce a reversal or compromise of the high patentability "standard expressed in the Constitution" (*Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) unvaryingly enforced here.

Rather, the categories of patentable subject matter set forth in 35 U.S.C. § 101 should be liberally construed to limit the number of inventors who have "no reason to apply for a patent" (See *Kewanee Oil Co. v. Bicron*, 416 U.S. 470, 483 (1974)) and promote progress by public disclosure of their inventions concomitantly with the rigorous enforcement of the constitutional patentability standard subsumed in 35 U.S.C. § 103.

ARGUMENT

I. The "Question Presented"

The "Question Presented" by the petition is "overly broad, which is calculated to magnify its importance"³ and permit petitioner to appeal to emotion, especially those vague and unreasoned fears about possible future achievements of microbiological research that seem to be fashionable at present.⁴ Asserting that the CCPA has made a "decision to extend the patent laws from the nonliving to the living" (P. Br. 38, n. 44), petitioner endeavors to distract this Court from both the specific

³ CCPA opinion, Pet. App. 45a. The "Question Presented" originated in the Petition for a Writ of Certiorari in No. 77-1503, *Parker v. Bergy*. On June 26, 1978, that Petition was granted, 438 U.S. 932, the judgment of the Court of Appeals was vacated and the cause remanded "for further consideration in light of *Parker v. Flook* . . . 437 U.S. 584."

⁴ See generally the brief *amicus curiae* on behalf of the People's Business Commission endorsed in part by Petitioner at P. Br. 19.

man-made microorganism at hand and the controlling, unambiguous, statutory language which has appeared in every patent law from 1790 to the present.⁵

As the CCPA correctly explained, *in this case* "[w]e are not dealing with all living things . . . all 'organisms'" (Pet. App. 45a). *Per contra*, at issue here is a man-made microorganism, which the court below held to be a "manufacture" within the penumbra of that term as used in apposite statutes since the inception of the patent system.

Petitioner acknowledges that the "CCPA . . . disavowed any intent to suggest the patentability of life forms other than microorganisms (Pet. App. 45a)" but justifies its uncabined "nonliving"-*"living"* synthesis by the assertion that such court "failed, however, to suggest why its conclusion concerning the scope of Section 101

⁵ Since enactment of § 1 of the Patent Act of 1790, 1 Stat. 109, "*any useful . . . manufacture . . . not before known or used*" (emphasis added) has been eligible for patent protection.

The Patent Act of 1793, 1 Stat. 318, section 1, permitted patents to be issued to persons who "have invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein. . . ." The superseding Act of 1836, 5 Stat. 117, provided, in section 6, for issuance of patents to persons "having discovered or invented any *new* and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter. . . ."

The 1870 Act, 16 Stat. 198, recodified as R.S. 4886 (1874), which subsisted without material change until the 1952 enactment of 35 U.S.C. § 101, provided that

Any person who has invented or discovered any *new* and useful art, machine, *manufacture*, or composition of matter . . . may . . . obtain a patent therefor.

The Reviser's Note for § 101 states:

Section 101 follows the wording of the existing statute as to the subject matter for patents, except that reference to plant patents has been omitted for incorporation in section 301 and the word "art" has been replaced by "process", which is defined in section 100. . . .

would not also apply to other living organisms. . ." (P. Br. 17, n. 16).

The CCPA, however, had been advised, and undoubtedly *knew*, even if it did not say so expressly, that single cell organisms are not only non-individualistic—i.e., they reproduce precisely⁶—but are also mindless, soulless and brainless.⁷

As the CCPA was also advised, it is now well established that living gene cells, as distinguished from higher multicellular organisms, obey the same laws of chemistry and physics, as nonliving cells.⁸

⁶ "Mitosis provides a precise and elegant mechanism for ensuring that two daughter cells each acquire a set, or sets, of chromosomes identical with those of the parent cell. Since, as we shall see, the chromosomes are indeed the bearers of the hereditary determinants, each daughter cell and its descendants will thus carry the same genotype as the initial parental cell. Such a population of genetically identical cells, derived from the multiplication of a single cell, is called a *clone*, while the process which gives rise to it is variously known as *mitotic*, *vegetative* or *asexual* reproduction. This is the way in which plant cuttings propagate themselves, damaged tissues are regenerated and bacteria multiply in a broth culture; in all these cases we expect, and nearly always find, that the new plant, tissue or bacterial culture is identical with the old one. On the contrary, when people or dogs or insects or many kinds of plant reproduce themselves we no longer anticipate that the offspring will be identical with each other and are rather surprised if they are. . ." Hayes, *The Genetics of Bacteria and Their Viruses*, 2d ed., John Wiley & Sons, Inc., New York (1968) at 11-12.

⁷ See the brief *amicus curiae* of the Regents of the University of California before the CCPA, pp. 14-16.

⁸ For example, Stent, *Molecular Genetics*, W. H. Freeman & Co., San Francisco (1971), at p. 28, notes that during the 1940's many physicists departed from their background and training to study gene cells "[i]nspired by the romantic notion of finding 'other laws of physics'" besides those then known and sums up "Alas, the physicists were to be cheated out of their reward: no 'other laws of physics had turned up along the way.' Instead . . . the making and breaking of hydrogen bonds seem to be all there is to understanding the workings of the hereditary substance." And Watson, *Molecular Biology of the Gene*, 2d ed., W.A. Benjamin & Co., New

Because microorganisms reproduce identically and function predictably once made, their patenting cannot have the social, moral or ethical overtones that might arise if dogs, cats, people, or honeybees were in issue. It follows that petitioner's arguments along these lines (e.g. P. Br. 10, 20) are irrelevant.

II. "Areas . . . Unforeseen by Congress"

35 U.S.C. § 101 in terms affords a possibility of patent protection to "[w]hoever invents or discovers *any* new and useful . . . manufacture. . . ." It does not restrict such a "manufacture" in any way, whether to "nonliving" subject matter or otherwise. Indeed, its use of the word "*any*" seems to be deliberately broad and all-inclusive, mirroring the equally wide scope of every predecessor statute since 1790.⁹

Nevertheless, petitioner invites this Court, in the guise of "strict construction" of this broadly worded statute, to imply—and thus legislate¹⁰—a "nonliving" limitation into the statutory scheme. Petitioner's pretext is its out-of-context interpretation of the caveat in *Parker v. Flook*, 437 U.S. 584, 596 (1978) that:

It is our duty to construe the patent statutes as they now read, in light of our prior precedents, and

York (1970) at p. 67, emphasizes that "not only . . . [are] the laws of chemistry . . . sufficient for understanding protein structure, but also . . . they are consistent with all known hereditary phenomena."

Highly skilled scientists in the field of microbiology have difficulty drawing bright lines between "living" and "nonliving" single cells. The question, e.g., of whether viruses are "living" or "nonliving" is not yet settled. See National Geographic, Vol. 150, pp. 355-95 at 386 (Sept. 1976).

⁹ See note 5, *supra*, p. 4.

¹⁰ "We should not read into the patent laws limitations and conditions which the legislature has not expressed." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933).

we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress. . . .

The petitioner's suggestion, of course, is that new microorganisms, like the new computer-implemented algorithm in *Flook*, were "wholly unforeseen" by Congress and therefore should not be patented. But in proper context, *Flook* cannot be read to require that the only specific new technology which is eligible for patenting is that foreseeable by Congress. Such a suggestion borders on impossibility. Were Congress blessed with such prophetic insights, patents would be superfluous.

Against the background of *Flook*, this Court necessarily meant its words "areas wholly unforeseen by Congress" to connote, e.g., abstract ideas and natural phenomena, which have always been held to be outside the ambit of § 101 and predecessor statutes. Congress has repeatedly placed its imprimatur upon this Court's pronouncements to the effect that § 101 excludes as unpatentable "a hitherto unknown phenomenon of nature,"¹¹ "a scientific truth or the mathematical expression of it,"¹² "a principle in the abstract . . . , an original cause, a motive,"¹³ "[p]henomena of nature, . . . mental processes . . . , abstract intellectual concepts,"¹⁴ and "a mere principle."¹⁵

In contrast to the algorithm that was at stake in *Flook*, the claims before the Court do not fall within this precluded realm. Rather, the present claims define a new,

¹¹ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

¹² *Mackay Radio and Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1938).

¹³ *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972), quoting from *LeRoy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852).

¹⁴ *Gottschalk*, *supra*, 409 U.S. at 67.

¹⁵ *Tilghman v. Proctor*, 102 U.S. 707, 729 (1880).

man-made, industrially useful microorganism not available in nature.

Petitioner's argument that this subject matter cannot be patented under the existing statute because "wholly unforeseen by Congress" suggests that our patent law is and has always been ineffective "to promote the progress of science and useful arts," as the Constitution directs it should. Manifestly, the Congress which formulated the 1790 statute authorizing "*any . . . useful manufacture*" to be patented *intended* that then unimagined technologies would qualify.¹⁶

III. Flook Mandates Affirmance

In contrast to *Flook*, where precedent "foreclose[d] a purely literal reading" (437 U.S. at 589) of the word "process"—new to the statute in 1952—the apposite decisions require that "manufacture" which has always been used by Congress to identify patentable subject matter be construed in the "ordinary sense of the word." *Ibid.*, at 588.

¹⁶ The legislative history of the 1930 Plant Patent Act emphasizes that:

[T]here are many instances where the provisions of the Constitution have been held to embrace affairs which, while literally within the meaning of a constitutional phrase, were not conceived of by the framers at the time that the Constitution was written. For example, the power to regulate interstate commerce, which was then mainly by horse or by rowboat or sailboat is now held by the courts to cover regulation of steam transportation, telegraphic communication, and even radio communication, matters beyond the wildest dreams of the framers of the Constitution. Senate Report 315, 71st Cong., 2d Sess. (1930), p. 9 and House Report 1129, 71st Cong., 2d Sess. (1930).

In *Graham v. John Deere Co.*, 383 U.S. 1, 19 (1966), the Court noted that:

Technology, however, has advanced—and with remarkable rapidity in the last 50 years. Moreover, the ambit of applicable art in given fields of science has widened by disciplines unheard of a half century ago. . . .

"It is elementary that '[t]he starting point in every case'—including this one—'involving the construction of a statute is the language of the statute itself,'" *Southeastern Community College v. Davis*, — U.S. —, 60 L.Ed.2d 980, 987-8 (1979); *Perrin v. United States*, — U.S. —, 48 L.W. 4009, 4111 (1979); *Andrus v. Allard*, — U.S. —, 48 L.W. 4013, 4014 (1979) and "that unless otherwise defined words will be interpreted as taking their ordinary, contemporaneous common meaning. *Burns v. Alcola*, 420 U.S. 570, 580-581 (1975)." *Perrin*, *supra*.

In 1931, this Court considered the question:

Is an orange, the rind of which has become impregnated with borax, through immersion in a solution, and thereby rendered resistant to blue mold decay, a "manufacture," or manufactured article, within the meaning of § 31, title 35, U.S.C.? ¹⁷

The word "manufacture" not being "otherwise defined" in the patent statutes, the court adopted the "ordinary, contemporaneous common meaning" of the word as set forth in the Century Dictionary and in its prior decisions in tariff cases, to answer the question in the negative:

"Manufacture," as well defined by the Century Dictionary, is "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." Also, "anything made for use from raw or prepared materials."

Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality or property. The added substance only pro-

¹⁷ *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931).

fects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore.

.....

[I]n *Anheuser-Busch Asso. v. United States*, 207 U.S. 556, 562, 52 L.ed. 336, 338, 28 S.Ct. 204, where it was claimed that corks for bottles which had undergone special treatment after importation thereby became articles manufactured in the United States, this court said: "Manufacture implies a change, but every change is not manufacture, and yet every change in an article is the result of treatment, labor and manipulation. But something more is necessary, as set forth and illustrated in *Hartman v. Wiegmann*, 121 U.S. 609, 30 L.ed. 1012, 7 S.Ct. 1240. *There must be transformation; a new and different article must emerge 'having a distinctive name, character or use.'*" (Emphasis added.) 283 U.S. at 11-13.

This construction of "manufacture" was unquestionably known to the Congress when the pertinent portion of the statute was re-enacted without change in 1952.¹⁸ The Court can thus "have no doubt that Congress has ratified the statutory interpretation of" *American Fruit Growers, Inc., supra*. *Douglas v. Seacoast Products, Inc.*, 431 U.S. 265, 278-9 (1977).

¹⁸ The 1952 Act was carefully nurtured through Congress by a group of patent lawyers and Patent Office employees, wholly cognizant of the decisional law, who sought no change in the word "manufacture," while concurrently causing the word "art" in the existing statute to be changed to "process". See, e.g., H.R. 1928, 82d Cong., 2d Sess., "Revision of Title 35, United States Code, PATENTS"; Report from the Committee on the Judiciary, House of Representatives, May 12, 1952, p. 2 (History of the Present Bill); Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1 (1954); Rich, *Congressional Intent or Who Wrote the 1952 Patent Act*, 61 Patent Procurement and Exploitation 70 (1963) and the Reviser's Note quoted *supra*, note 5, page 6.

Chakrabarty's new and useful microorganism is indeed a "transformation; a new and different article [microorganism] 'having a distinctive name, character or use,'" i.e., to clean up spilled oil—and, hence, is a "manufacture" within the meaning of § 101.¹⁹

IV. The Real "Legislative History" Mandates Affirmance

The settled and clear meaning of the word "manufacture" as used in § 101 should be dispositive without any reference to legislative history.

Petitioner, however, disdaining any reference to § 101's predecessors, the "contemporaneous . . . meaning" of the terms, or *American Fruit Growers, Inc.*, posits its case for extensive reference to a synthetic "legislative history" (see P. Br. 11, 21, *et seq.*) solely on its *ipse dixit* that the "key words manufacture or composition of matter . . . hardly define themselves" (P. Br. 30).

This excursion into a constructed legislative history is both unwarranted and misdirected. The practical application of the existing patent laws largely excluded "life

¹⁹ The petitioner admits as much:

Certain strains of *Pseudomonas* bacteria existing in nature are capable of degrading by enzymatic reactions a particular component of a complex hydrocarbon, such as crude oil, but no known naturally-occurring bacterium can degrade more than one such component. Chakrabarty employed so-called "genetic engineering" to develop a *Pseudomonas* bacteria capable of degrading more than one component of crude oil (Pet. App. 142a-143a).³

³ Plasmids, which are hereditary units separate from the chromosomes, carry the hydrocarbon-degrading capacity of the cell. Chakrabarty utilized a process of natural conjugation (A. 41, 46) to effectuate the transfer to a single cell of plasmids from various known strains of bacteria, each known to have a specific capacity to degrade a particular component of crude oil (A. 46-50). The resulting organism, which Chakrabarty seeks to patent, is a bacterium with increased hydrocarbon-degrading capacities due to the different kinds of plasmids it contains (Pet. App. 143a). (P.Br. 6)

forms," not because they were alive²⁰—a factor not mentioned by the Congress²¹—but because they were either "products of nature" and hence not "new" (R.S. 4886; 35 U.S.C. § 101) or because the statutory requirements for a detailed written description and for precise claiming (R.S. 4888; 35 U.S.C. § 112) could not be satisfied, *inter alia*, because such inventions did not reproduce true to form, *i.e.*, were not "stable".²²

A. Natural Products are not "New"

The truism that natural products, *per se* and as synthesized by man, are not "new" and hence constitute unpatentable subject matter dates at least from the 1884

²⁰ Petitioner argues that:

Inanimate inventions relating to agriculture had always been covered by the patent law; the *only* reason that legislation [*i.e.*, the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act] was required was *because the subjects to be newly protected were alive*. . . . That legislation does not encompass Chakrabarty's invention; accordingly, it is not patentable. (P.Br. 11)

.....

The very fact that Congress [in 1930] added these [plant patent] provisions to the predecessor of Section 101 strongly indicates a congressional understanding that the terms "manufacture, or composition of matter" did not extend to living things, for otherwise the new authorization . . . would have been redundant. . . .

.....

Similarly the Plant Variety Protection Act . . . enacted in 1970 . . . would be redundant under the reading of section 101 adopted by the court below, for under that reading living things already were patentable as "'manufacture[s], or composition[s] of matter.'" (P.Br. 22-23)

²¹ As the CCPA put it, the petitioner's argument attributes to Congress an intent that its "members did not themselves state" (Pet. App. 51a).

²² Higher organisms do not reproduce truly, and hence remain unpatentable. See Hayes, *supra*, n. 6, p. 7.

decision of this Court in *Cochrane v. Badische Anilin and Soda Fabrik*, 111 U.S. 294.²³

Most "life forms", at least prior to 1930, were products of nature which failed to satisfy the statute's requirement that only "new" manufactures and compositions of matter could be patented.²⁴ Indeed, as petitioner admits, the 1930 Plant Patent Act "carefully distinguished between products of nature . . . and products of man" (P. Br. 33).²⁵

²³ According to the description in No. 95465, and in No. 4321, and the evidence, the article produced by the process described was the alizarine of madder, having the chemical formula $C_{14}H_8O_4$. It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction to being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially for the first time from anthracene, if it was set forth as alizarine, a well known substance. The Word Paper Patent, 23 Wall., 566, 593 [90 U.S. XXIII, 31, 39] 111 U.S. at 311.

This ruling sustains an averment in the answer that "alizarine is a natural product . . . ; that it is not a composition of matter within the meaning of the statute [predecessor of § 101, see n. 5, *supra*, p. 6], but has been well known in the arts," *i.e.*, not "new". 111 U.S. at 297.

The same rule was applied, in 1889, to natural plant products in *Ex Parte Latimer*, 1889 Dec. Comm. Pat. 423.

²⁴ As the CCPA points out: "The secondary purpose of the Plant Patent Act was to avoid the judicial interpretation which had been placed on then-existing patent laws that *products of nature* are not statutory subject matter. Until the time that Burbank made famous the art of plant breeding, plants were regarded as products of nature, unaffected by the hand of man, and thus not subject to patent protection" (Pet. App. 59a, citing Wegner, *The Patentability of "New Manufactures"—The Living Invention*, "The Product of Nature of Early Days," 1978 Patent Law Conference Coursebook (BNA) 274-80) (emphasis by the court).

²⁵ P.Br. 33, n. 40 adverts to "work in plant genetics and breeding," *i.e.*, man-made plants, which substantially preceded the 1930 Plant

These same considerations devitalize petitioner's argument premised on two casual references from the legislative history suggesting that Congress, in adopting the 1930 Patent Act, was discriminating broadly between animate and inanimate things.²⁶

Applying the same reasoning to bacteria, the CCPA in 1974 presumed "without deciding" that the microorganism recited in the process claim before it was not patentable because it was a "product of nature" and hence "lacked novelty".²⁷

Patent Act to invite the spurious inference that plants are excluded from the existing statute *solely* because they are alive. However, "living organism" inventions were in no event patentable because of inability to satisfy the detailed written description and precise claiming requirements of R.S. 4888.

²⁶ The quotation at P.Br. 32 from H.R. Rep. No. 1129 at p. 7 and S. Rep. No. 315 at p. 6 which adverts to a "distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a . . . mineral," is followed in the next sentence by an explanation of the "distinction," in effect, that the "mineral" is an unpatentable product because it is "created wholly by nature unassisted by man," whereas new asexually propagated plants are not "reproduced by nature unaided by man."

Secretary of Agriculture Hyde's understanding (see P.Br. 24, *et seq.*) that "the patent laws . . . at the present time . . . cover only inventions or discoveries in the field of inanimate nature" is meaningful in the same "product of nature" context and does not at all require that the constraint deemed by Hyde to restrict patents to inanimate things was consequent solely, or at all, from the fact that *animate* things are *alive*.

²⁷ The CCPA's decision in *Application of Mancy*, 499 F.2d 1289, 1294 (1974) states in dicta:

Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain . . . is, as we understand it, a "product of nature"

In this case, rebutting a representation in the first Bergy petition, No. 77-1503, p. 6 that the CCPA in *Mancy* "suggested" that "living things" are not patentable, the CCPA was at pains to state the obvious—i.e., "we now make it explicit that the thought underlying

B. The Written Description and Precise Claiming Requirements of R.S. 4888

R.S. 4888, the predecessor to 35 U.S.C. § 112 (1952), provided that

Before any inventor or discoverer shall receive a patent . . . he shall . . . file in the Patent Office a written description of the same, and the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same . . . and he shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery. . . .

The fact that plants were not amenable to the detailed description and to the precise claiming requirements of that statute was called to the attention of the Congress by a memorandum from the Commissioner of Patents, Thomas E. Robertson, to the Secretary of Commerce, R. P. Lamont, which appears in the legislative history:

Further, and more important, there at once arises the difficulty of defining in a written document which must be printed, both as constituting part of the

our presumption that Mancy could not have obtained a claim to the strain of microorganism he had described was simply that it *lacked novelty*" (emphasis by the court) (Pet. App. 46a).

Nevertheless, to somehow justify its reiteration of the same misrepresentation, petitioner now says that Mancy's microorganism "was . . . like Bergy's biologically pure culture . . . which the same judges who decided Mancy found 'did not define a product of nature' (Pet. App. 39a)" (P.Br. 14, n. 13).

There is no such inconsistency. *Mancy* does not advert to a "microbiologically pure culture" as claimed by Bergy, or raise the issue of whether such a culture is a "product of nature." As the petitioner stresses, "the question involved" in both Bergy and Chakrabarty "is an issue of first impression" (P.Br. 13).

patent and as constituting a publication available for search and distribution, the differences which identify a new variety from previously known varieties. . . .

If it is not possible by ordinary description of the physical qualities of the plant, or the fruit, or the bloom, or all three, to so accurately define this new variety that it can be differentiated from all known varieties and from all subsequently created new varieties, then it is difficult to see how a patent to be granted would comply with the other provisions of the statutes, namely, that the inventor must describe his invention in full, clear, concise and exact terms.²⁸

Congress' response, concurrently with the amendment of R.S. 4886, to permit the patenting of "any new . . . asexually reproduced . . . distinct and new variety of plant, other than a tuber-propagated plant" was to also amend R.S. 4888 to accommodate the description problem by providing that "No plant patent shall be declared invalid on the ground of noncompliance with this section if the description is made as complete as is reasonably possible."

Shortly thereafter, the Patent Office practice with respect to the claiming requirement of R.S. 4888 was changed to provide, as later codified in 35 U.S.C. § 162 (1952), that "The claim in the specification shall be in formal terms to the plant shown and described."²⁹

Apparently, to buttress its contention that Congress in 1930 "made a limited class of living things patentable"

²⁸ A Bill to Provide for Plant Patents: Hearings on H.R. 11372 before the Commissioner of Patents, 71st Cong., 2d Sess. 7 (1929-30) (statement of Hon. Fred S. Purnell).

²⁹ The Reviser's Note states that "The second [above-quoted] paragraph is not in the [prior] statute [R.S. 4888] but represents the actual practice."

(P. Br. 35), by inference a class which *excludes* microorganisms, petitioner says that the Plant Patent Act "provided patent protection only to *certain* (P.Br. 33) man-made plants. The exclusions—only of *non*-asexually reproduced plants and "tuber-propagated" plants—were explained by Congress on other grounds:

All plants must be asexually reproduced *in order to have their identity preserved*. This is necessary since seedlings either of chance or self-pollination from any of these would not preserve the character of the individual.³⁰

. . . .

Substantially the only plants covered by the term "tuber-propagated" would be the Irish potato and Jerusalem artichoke. This exception is made because

³⁰ Petitioner acknowledges that, "the objection to including sexually reproduced plants under the 1930 Plant Patent Act had been that new varieties could never be reproduced true-to-type through seedlings. S.Rep. No. 315, *supra* at 4; H.R. No. 1129, *supra* at 4-5" (P.Br. 27, n. 31).

This same fact is acknowledged in the 1968 Congressional hearings on patent law revision. "Asexual reproduction is specified in the Plant Patent Act because this method of propagation generally insures the continuation of the new and distinct characteristics of the plant through succeeding generations." ("Patent Law Revision," Hearings Before the Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, U.S. Senate, 90th Cong., 2d Sess., part 2, January 30, 31 and February 1, 1968, p. 651.)

In 1940, the CCPA held that bacteria, which *do* reproduce true to form, are not plants and hence not patentable under the 1930 Act. *In re Arzberger*, 112 F.2d 834. The decision has been criticized. See Parker, 22 J.Pat.Off.Soc'y 622 (1940); Note, 33 Minn.L.Rev. 430 (1949); Daus, 10 Idea 87 (1966) and Irons and Sears, *Patents in Relation to Microbiology*, 29 Ann.Rev. of Microbiology 319 (1975).

The latter paper notes that the Arzberger patent application contained a single claim to a defined "bacteria" and that the CCPA acknowledged that bacteria "are scientifically classified as plants" but concluded that "Congress, in the use of the word 'plant' was speaking 'in the common language of the people' and did not use the word in its strict scientific sense." 112 F.2d at 838.

this group alone, among asexually reproduced plants, is propagated by the same part of the plant that is sold as food. H.R. Rep. No. 1129, 71st Cong., 2d Sess. (1930) 4, 6; S.Rep. 315, 71st Cong., 2d Sess. (1930).

The 1970 Plant Variety Protection Act followed only after the evolution of the art obviated the same description problem with respect to seeds:

In the 37 years which have passed since the enactment of the Plant Patent Act improved breeding techniques and seed multiplication procedures have become established whereby many plant varieties may be reproduced from seeds true to form. Such ability of plant varieties to reproduce true to form from seeds is not acknowledged in existing legislation, such as the Federal Seed Act which was enacted August 1939, and seed certification. It accordingly follows that the distinction drawn in the Plant Patent Act between plants which reproduce asexually and plants which reproduce sexually is artificial, and that the act should be broadened to include plants which reproduce sexually.³¹

As in the case of plant patents, the description requirements for a plant variety protection certificate are generalized. Only "a description of the variety setting forth its novelty and a description of the genealogy and breeding procedure, when known" is required, 7 U.S.C. § 2402. Nor is any formal, precise claim required as in § 112 of the patent statutes.³²

³¹ Statement of Floyd S. Ingersoll, "Patent Law Revision," Hearings Before the Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, U.S. Senate, 90th Cong., 2d Sess., Pursuant to S.Res. 27 on S. 2, S. 1042 S. 1377, S. 1691, S. 2164 and S. 2597, Part 2, January 30, 31 and February 1, 1968, pp. 638, 640.

³² The *Plant Variety Protection Office Journal*, Vol. 7, No. 3 (July-Sept. 1979) includes the following certificates:

V. Accommodation of Microbiological Process Patents to the Requirements of 35 U.S.C. § 112

Patent applications pertaining to microbiological processes encountered problems similar to those which initially precluded the patenting of asexually reproduced plants and seeds. Such inventions, particularly those in which the sole novelty resided in the microorganism utilized, could not be patented unless and until a procedure for satisfying the written description and precise claiming requirements of the statute could be satisfied.³³

By 1970, these difficulties had been overcome—not by amendment of the statute—but by Patent Office regulations requiring the deposit, in a collection accessible to the public, of a culture of the microorganism at the time or before the patent application is filed.³⁴

The CCPA dealt with the matter, with specific reference to the analogous problem as regards asexually reproduced plants, in *Application of Argoudelis*, 434 F.2d 1390 (1970). In *Argoudelis*, the claimed invention included a process for producing an antibiotic by fermenta-

No. 7700106 for "Wheat" identified as "5466"—"5466" most closely resembles '5422'; however, '5466' has an inclined spike at maturity, where as the spike of '5422' is erect."

No. 7900017 for "Lettuce" identified as "Coolguard"—"Coolguard" most closely resembles 'Winterhaven' and 'Vanguard'; however, 'Coolguard' has a lighter yellow flower color than 'Winterhaven' and 'Vanguard' (4D VS 6C and 6D Royal Horticultural Society Colour Chart)."

³³ See generally, Levy and Wendt, *Microbiology and a Standard Format for Infra-Red Absorption Spectra in Antibiotic Patent Applications*, 37 J.Pat.Off.Soc'y 855 (1955).

³⁴ Under the present Patent Office practice, the deposit must be irrevocable, of a permanent character and made under conditions which insure free availability of samples of the microorganism to the public at the time that a patent actually issues. Section 608.01(p) of the Manual of Patent Examining Procedure (Rev. 39, Jan. 1974).

Such deposits were made by Chakrabarty (Pet. App. 31a) and Bergy (P.Br. 4, n. 1).

tion with the microorganism *Streptomyces sparsogenes* var. *sparsogenes*. The Patent Office had rejected the claims "as based on a deficient disclosure [of the microorganism] under 35 U.S.C. § 112" (434 F.2d at 1391-2). The CCPA held:

Appellants, however, because of the particular area of technology involved, cannot sufficiently disclose by written word how to obtain the microorganism starting material from nature.

It has been pointed out in the Amicus Curiae brief that the same predicament exists in the case of asexually reproduced plants. In regard to plants, a general dispensation from the requirements of § 112 has been accorded by 35 U.S.C. § 162. It is urged that the same should be true here. We do not believe that a general dispensation from the statutory requirements of § 112 in the case of microorganisms is necessary, desirable, or within the province of this court to grant. Our task here is not to decide what the general rule should be or to create exceptions to the provisions of § 112, but rather to interpret and apply § 112 to the facts of the case before us. . . .

As mentioned, a unique aspect of using microorganisms as starting materials is that a sufficient description of how to obtain the microorganism from nature cannot be given. . . .³⁵ The microorganism involved here, of course, was not known and available to the workers in the art since it was newly discovered by appellants.

³⁵ The fact that a new microorganism can be fully "described" only by a reference to a physical specimen, rather than in words, makes it particularly susceptible to suppression as trade secrets known to an elite few.

It is important to the public that the patent incentive be available to the inventors of today's new man-made microorganisms, such as that of Chakrabarty, so as to insure that the existing new knowledge they represent is not suppressed, but is disclosed to the public by the normal operation of the patent laws.

Faced with this problem, and in response to the requirements of § 112 for an enabling disclosure, appellants deposited cultures of their microorganism in a public depository in the United States. This was done before the United States patent application was filed. The written description as originally filed included the name of the depository and its designation of the deposit, in addition to a complete taxonomic description of the microorganism and detailed disclosure of the process for producing the antibiotic from the microorganism. The cultures are to be made available to the public upon issuance of a United States patent which refers to such deposit and prior to issuance of said patent under the conditions specified by Rule 14. Appellants state that the practice of depositing cultures in a public depository has been used for over fifteen years.

It is our opinion that this procedure meets the requirements of 35 U.S.C. § 112. . . . (Footnote omitted.) 434 F.2d at 1392-3.

This procedure is equally effective to provide a "written description" adequate under § 112 *without regard to whether* the claims cover a microorganism *per se*, a composition of which the microorganism is a major ingredient or a process for using the microorganism to produce a desired product.³⁶

³⁶ Historically, working models were required by the Patent Office as an aid to describing mechanical and electrical devices. The Patent Office up to the present time requires drawings under 35 U.S.C. § 113 and 37 C.F.R. § 1.81 in any case which admits of them, for the same purpose of augmenting written description. In addition, working models (37 C.F.R. § 1.91) or specimens of chemicals (37 C.F.R. § 1.93) may be required to be furnished if the Patent Office deems either would aid in promoting understanding of the invention. A similar situation prevails with respect to asexually propagated plants. Drawings are required in every application (37 C.F.R. § 1.165) and specimens, at any growth stage, may be required at the discretion of the Patent Office (37 C.F.R. § 1.166).

VI. Affirmance is Appropriate Despite Incorrect Reasoning Below

The Court should not be deflected from affirming the judgment below—the only issue before it—by the significant errors in legal analysis which permeate the majority opinion. As cogently evidenced by the consistent reversal of its decisions here,³⁷ the CCPA tends toward legal error and has long waged war against this Court's venerable and unvaried interpretations of the patent laws. One of the most tenacious, maintained errors is an insistence that the 1952 Patent Act significantly changed the law, disqualifying as precedent the pre-1952 opinions of this Court and lower federal courts and even of the CCPA itself.³⁸

³⁷ See *Brenner v. Manson*, 383 U.S. 519 (1966); *Gottschalk v. Benson*, 409 U.S. 34 (1972), *Dann v. Johnston*, 425 U.S. 219 (1976) and *Parker v. Flook*, 437 U.S. 584 (1978).

³⁸ H.Rep. 1928, 82d Cong., 2d Sess. (1952), which accompanied the 1952 Patent Act at passage, emphasized that notwithstanding "a number of changes in substantive statutory law"—one of the main ones being the inclusion of "a requirement for invention in § 103"—"the principal purpose of the bill is the codification of title 35, United States Code and involves simplification and clarification of language and arrangement, and elimination of obsolete and redundant provisions . . ." (p. 5). See also S.Rep. No. 1979, 82d Cong., 2d Sess. (1952).

Disdaining this and other similar aspects of that Act's legislative history, the CCPA's Judge Rich has authored a series of articles strongly advocating the erroneous legal thinking that characterizes many CCPA opinions, including the majority opinion below. In Rich, *Congressional Intent or Who Wrote the 1952 Patent Act*, 61 Patent Procurement and Exploitation 70 (BNA 1963), the judge alleged that the 1952 Act was intended to create "law superior to that which may be derived from any prior court opinion." As with this one, the themes of other Rich articles can often be gleaned from their titles. See Rich, *Principles of Patentability*, 28 G.W.L.Rev. 393 (1960); Rich, *The Vague Concept of "invention" as Replaced by § 103 of the 1952 Patent Act*, 8 Idea 136 (1964); Rich, *Laying the Ghost of the "Invention" Requirement*, 1 APLA Q.J. 26 (1972); Rich, "Change", 2 APLA Q.J. 214 (1974).

Wrote Judge Rich in 1975, "[i]n the only two CCPA patent cases so far decided by the Supreme Court on certiorari . . . the

Perpetuating that error, the opinion below construes 35 U.S.C. § 101 and § 103 in derogation of this Court's applicable precedent before and after 1952.

In regard to § 103, this Court has held repeatedly that the judicial test of "invention" and the "unobviousness" language of § 103 commonly implement the "standard expressed in the Constitution [which] may not be ignored," *Graham v. John Deere Co.*, 383 U.S. 1, 6 and, hence, are but different labels for the same unvarying patentability standard.³⁹

Similarly, the category "new" in § 101's list of six categories of subject matter that may be patented⁴⁰ accords with "the limits of the constitutional grant" which

CCPA has been reversed. Erroneously, of course. I have a favorite axiom: "The higher you go, the less they know." Rich, *How Systematic is the Patent System?*, 57 J.Pat.Off.Soc'y 696 (1975).

³⁹ *Graham* emphasizes that the patentability "standard [is] expressed in the Constitution and it may not be ignored" (*ibid.* at 6), and that 35 U.S.C. § 103 "comports with the constitutional strictures" (*id.* at 17) only if construed to embrace that standard which "has remained invariable in this Court" (*id.* at 19), as distinguished from the "relaxed standard" (*id.* at 19) which the Court was unsuccessfully "urged to find".

In 1976, the Court, reaffirming *Graham*, emphasized again that:

As a judicial test 'invention'—i.e., 'an exercise of the inventive faculty,' *McClain v. Ortmyer*, 141 U.S. 419, 427 . . . (1891)—has long been regarded as an absolute prerequisite to patentability. See, e.g., *Keystone Driller Co. v. Northwest Engineering Corp.*, 294 U.S. 42 . . . (1935); *Sharp v. Stamping Co.*, 103 U.S. 205 . . . (1881); *Hotchkiss v. Greenwood*, 11 How. 248 . . . (1851).

and that in *Graham*:

We held that § 103 "was not intended by Congress to change the general level of patentable invention" but was meant "merely as a codification of judicial precedents. . . ." *Dann v. Johnston*, 425 U.S. 219, 225-6 (1976).

⁴⁰ I.e., subject matter that is (1) "new," and (2) "useful," and is also a (3) "process," (4) "machine," (5) "manufacture," or (6) "composition of matter".

preclude Congress from "authoriz[ing] the issuance of patents whose effects are to remove existent knowledge from the public domain" (*ibid.*).⁴¹

Notwithstanding this settled law, the CCPA has held that "the Constitutional clause . . . set no standards for the patentability of individual inventions" (Pet. App. 8a-9a). It has charged that the "briefs filed by the Solicitor General" in *Flook* "badly, and with a seeming sense of purpose, confuse the statutory-categories requirement of § 101 with a requirement for the existence of 'invention'" (Pet. App. 17a) and advance "subversive nonsense" (Pet. App. 19a) which this Court "unfortunately and apparently unconscious[ly] though clear[ly]" adopted in *Flook* (Pet. App. 10a).

Whatever "nonsense" may be involved is found, not in this Court's *Flook* opinion or in the associated briefs of the Solicitor General but in the bankrupt challenges to settled law advanced by the CCPA majority.

That majority opinion emphasizes the "nonsense" that:

*Prior art is irrelevant to the determination of statutory subject matter under § 101. An invention can be statutory subject matter and be 100% old.*⁴²

⁴¹ Thus, the Court, following *Graham*, held the patent at issue invalid in *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62, n.4 (1969) for absence "here [of] the element 'new' . . . [f]or . . . the combination patent added nothing to the inherent characteristics . . . of the [prior art]."

See also, *Cochrane v. Badische Anilin*, *supra*, p. 15, n. 23, in which the Court held that a dye product which had been in the public domain for years was not a "new" composition of matter within the meaning of the 1870 Act.

⁴² Compare the contrary rulings of this Court in *Anderson's-Black Rock*, *supra*, p. 26, n. 41, and in *Cochrane*, *supra*, p. 15, n. 23. See also the House Report on the 1952 Patent Act, quoted *supra*, n. 38, p. 24.

devoid of any utility⁴³ or entirely obvious. (Emphasis by the court; Pet. App. 19a.)

In furtherance of its charges against the Solicitor General, but with no reference to this Court's contrary rulings in *Graham*, *Dann*, and *Anderson's-Black Rock*, *supra*, and in *Sakraida v. Ag Pro*, 425 U.S. 273 (1976), the CCPA asserts that "there has not been a requirement for 'invention' in the patentability sense in the laws since 1952—the requirement was replaced by the § 103 requirement for nonobviousness" (Pet. App. 17a).⁴⁴

These CCPA errors should be repudiated firmly by this Court, as they have been in the past. It is singularly important, however, that the Court not become so intent on dispelling these errors that it also reverses the CCPA's judgment.

CONCLUSION

The public policy of the patent system is to "promote progress of science and useful arts," by inducing timely public disclosure of technologically significant inventions. Within the constitutional and statutory framework, that policy is best served by a liberal construction of § 101's categories of patentable subject matter. Otherwise, the inventors of the most progressive new discoveries will be among those who have "no reason to apply for a patent"

⁴³ In contrast, this Court in *Brenner*, *supra*, held flatly that the word "useful" in § 101 continues "the concept of utility [which] has maintained a central place in all of our patent legislation, beginning with the first patent law in 1790." 383 U.S. at 529, and that "Congress has struck the balance on the side of nonpatentability unless 'utility' is shown." *Ibid.* at 535.

⁴⁴ These contentions are best understood in the context of a continuing effort, endorsed by Judge Rich and the CCPA, to induce this Court to reverse its ruling in *Graham* and "find in § 103 a relaxed standard" consequent from the alleged "substitution" of "unobviousness" for "invention" as the dispositive patentability criterion.

because those discoveries fall "in the area of nonpatentable subject matter." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 483 (1974).

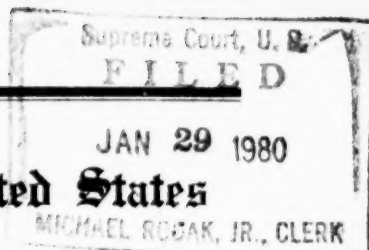
The petitioner itself has properly accommodated the requirements of § 112 to microbiological process inventions; hence, such constraints should no longer preclude the patenting of manufactured microorganisms. The petitioner's invitation to this Court to impose such artificial constraints, in derogation of *Dubilier, supra*, p. 8, n. 10, by reading "into the patent laws" a "nonliving" limitation for "manufacture[s]," "which the legislature has not expressed," should be rejected.

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IN THE
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OCTOBER TERM, 1979



No. 79-136

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TRADEMARKS, *Petitioner*

v.

ANANDA M. CHAKRABARTY, *Respondent*

**On Writ of Certiorari to the United States
Court of Customs and Patent Appeals**

**BRIEF ON BEHALF OF THE PHARMACEUTICAL
MANUFACTURERS ASSOCIATION,
AMICUS CURIAE**

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**BRIEF ON BEHALF OF THE PHARMACEUTICAL
MANUFACTURERS ASSOCIATION,
AMICUS CURIAE**

I. INTRODUCTION AND INTEREST OF AMICUS CURIAE

THREAT TO FISHING, TOURISM
OIL SPILL PERILS FRENCH COAST

Thousands of barrels of oil from the wrecked American-owned supertanker Amoco Cadiz swept down the picturesque Brittany coast yesterday, blackening beaches and menacing ports along 40 miles of shorelines.

.

Officials fear the spill could become France's worst ecological disaster before it is brought under control.

The Washington Post, Sunday, March 19, 1978, at A-1.

Given the magnitude of this disaster, one would have thought that the discovery of a means for mitigating or eliminating totally the effects of such an oil spill would be entitled to patent protection, assuming the requisite novelty and nonobviousness. In *Application of Chakrabarty*, 596 F.2d 952 (C.C.P.A. 1979), a four-judge majority of the U.S. Court of Customs and Patent Appeals (CCPA) again¹ held exactly that: that the inventor of a new strain of microorganism (bacteria) alleged to be capable of simultaneously degrading several different components of crude oil, with the result that degradation occurs more rapidly, was entitled to patent protection. On October 29, 1979, this Court granted the Government's petition for a writ of certiorari in the *Chakrabarty* case.

Petitioner, supported by *Amicus* People's Business Commission (PBC), urges this Court to reverse the CCPA determination of patentability. It is their position that a patent on the Chakrabarty microorganism should be denied solely because that organism is "living." This contention is made notwithstanding the

¹ The court had earlier reached the same conclusion in *Application of Chakrabarty*, 571 F.2d 40 (C.C.P.A. 1978), *vacated and petition for cert. dismissed*, 99 S. Ct. 44 (1978). The CCPA recalled its original mandate in the *Chakrabarty* case to allow that decision to be reconsidered along with *Application of Bergy*, 563 F.2d 1031 (C.C.P.A. 1977), *vacated sub. nom. Parker v. Bergy*, 438 U.S. 902 (1978). This Court vacated the original decision in *Bergy* and remanded for consideration in light of *Parker v. Flook*, 437 U.S. 584 (1978).

grudging concession of PBC that the granting of patents on subject matter such as was invented by Chakrabarty would generate a greater momentum in research and development leading to the rapid application of this technology in many aspects of the nation's economic life (PBC Brief at 3).

Both Petitioner and PBC urge the same result for the biologically pure microorganism culture forming the subject matter of the Bergy invention. That case has been mooted by virtue of the abandonment of the underlying patent application, and the appeal with respect to it has been dismissed.²

Amicus Pharmaceutical Manufacturers Association (PMA) has a deep interest in the aforesaid position taken by Petitioner and PBC. More specifically, the Chakrabarty microorganism resulted from the newly emerging group of technologies sometimes referred to as "genetic engineering." These technologies include, *inter alia*, mutation and isolation of organisms and recombinant DNA techniques.³ It has been predicted that "the first major commercial impact of present-day DNA research will be seen in the pharmaceutical industry."⁴

While the Chakrabarty microorganism is economically important for what it consumes, other modified organisms are and will become important for the ma-

² In light of the dismissal of the *Bergy* appeal, discussion in this brief will refer to that subject matter only to the extent it is helpful in understanding the issues in the present appeal.

³ *Where Genetic Engineering Will Change Industry*, Business Week, October 22, 1979, at 160.

⁴ Tullis, *Recombinant DNA Research*, Morgan, Stanley & Co. Investment Research Note, September 11, 1979, at 1.

terials they produce. Where insulin for diabetic treatment has formerly been extracted from animal pancreases, hitherto unavailable *human* insulin is now being produced by a modified microorganism.⁵ Where treatment of one child for dwarfism previously required extraction of human growth hormone from 50 cadavers per year, that same hormone can now be synthesized through the use of a modified microorganism.⁶ In the offing is the synthetic production by microorganisms of interferon, a presently expensive natural body substance which stimulates immune reactions and which may be effective in treatment of numerous viral diseases and possibly in cancer therapy. Also in the offing is microbiological production of human blood fractions, including those fractions used to treat hemophilia which must now be produced from pooled human plasma sources.⁷

Potential applications of this new technology in nonpharmaceutical areas include industrial waste dis-

⁵ Begley et al., *The DNA Industry*, Newsweek, August 20, 1979, at 53. Bacterial insulin production is expected to be 30 to 50% cheaper than conventional technology. Wade, *Recombinant DNA: Warming Up for the Big Payoff*, 206 Science 464 (1979).

⁶ Begley, *supra* note 5, at 53. Indeed, researchers using recombinant DNA techniques produced as much of a brain hormone overnight in a 2-gallon jug of altered bacterial culture as Nobel laureates Guillemin and Schalley (1977) were able to extract in a year-long process from the brains of 500,000 sheep. *Hearings on Regulation of Recombinant DNA Research before the House Subcommittee on Science, Technology and Space*, 95th Cong. 1st Sess. 56 (1977) (Statement of Paul Berg).

⁷ Tullis, *supra* note 4, at 5. Indeed, synthetic interferon is no longer simply in the offing. As this brief was being prepared, newspapers across the country reported that research on interferon had come to fruition. See, e.g., Russell, *Disease Fighter Interferon Synthesized*, The Washington Star, January 17, 1980, at A-1.

posal, cost-efficient production of alcohol from inexpensive biomass for use in gasohol production and the production of synthetic organic chemicals of all types for the chemical industry.⁸ It has been said that the promise is nothing less than "the possibility of building a sustainable future based on renewable resources."⁹ In terms of economics, we are talking about "billion-dollar possibilities."¹⁰ Pharmaceutical companies will occupy a unique position even in these non-pharmaceutical areas, since "except for the drug companies, which use large-scale fermentation processes to manufacture drugs, most companies have little or no experience with culturing living organisms."¹¹

The Pharmaceutical Manufacturers Association is a voluntary, non-profit association composed of 143 members engaged in the discovery, development, manufacture and marketing of prescription and ethically promoted drugs, medical devices and diagnostic products. Some of PMA's members are engaged in genetic engineering research, and it is probable that others will soon be entering this promising field. Since the United States pharmaceutical industry has been greatly encouraged by the patent protection hitherto afforded the fruits of its research, *Amicus* PMA files this brief on behalf of its members in order to assure the continued availability of meaningful patent pro-

⁸ Tullis, *supra* note 4, at 3; Business Week, *supra* note 3, at 160, 168.

⁹ Business Week, *supra* note 3, at page 160, quoting Zsolt Harsanyi of the Office of Technology Assessment.

¹⁰ Begley et al., *supra* note 5, at 53.

¹¹ Business Week, *supra* note 3, at 172. See also Tullis, *supra* note 4, at 6.

tection as we stand on the threshold of development of this potentially revolutionary technology.

All parties have consented to the filing of this *Amicus* brief by letter, the originals of which are being filed concurrently with the Clerk.

II. SUMMARY OF ARGUMENT

This case does not involve a number of issues raised both by *Amicus* PBC and Petitioner.

It does not involve the patenting of phenomena of nature or the like. Petitioner expressly conceded that the Chakrabarty microorganism is not a product of nature, and prior decisions of this Court have clearly indicated that such a microorganism is not unpatentable as a product or phenomenon of nature.

Whether or not the technology of genetic engineering is in the public interest should have no impact on the outcome of this case, since (1) there is no doubt that the granting of patents on living organisms will promote the progress of the useful arts, (2) the absence of patents on living organisms will not preclude research or commercial exploitation in areas such as genetic engineering absent legislation by Congress, and will only serve to limit public disclosure of the technology, and (3) the "sky-is-falling" arguments made against the patenting of living organisms could have been made against a multitude of inanimate technologies which have contributed heavily to this country's progress.

The potential patenting of higher life forms is not before the Court in this case, and need not be decided in order to resolve the issues presented by the Chakrabarty invention. Aside from the fact that courts do

not shrink from difficult decisions, the all-or-nothing argument of Petitioner and *Amicus* PBC is unsound.

The practical success or failure of the patent acts covering plants is irrelevant to the issues in this case and, in any event, the argument grounded on its alleged failure is based on faulty factual assumptions.

The holding below is totally compatible with an almost 200-year old statutory scheme and the historical application of the patent laws. Aside from the fact that the holding does not represent an extension of the patent laws, the statutory scheme since 1790 has contemplated patenting of new and unforeseen technologies, has been applied to new technologies as they developed, including those related to living organisms, and its application to new and unforeseen technologies best achieves the constitutional purpose of promoting the useful arts.

Contrary to Petitioner's view, it was not the general understanding prior to the decision below that legislation was needed if the patent laws were to be applied to microorganisms.

Congress did not intend to exclude microorganisms from the scope of 35 U.S.C. § 101. Petitioner's position that the Plant Patent Act of 1930 and the Plant Variety Protection Act preclude construction of Section 101 to cover microorganisms is based on fallacious assumptions and unduly expansive interpretations of the legislative history of these acts. Not only did these acts have nothing to do with microorganisms, but the views of a subsequent Congress are of little value in determining the intent of a prior Congress. Moreover, the collateral elements of this legislative history do not establish a Congressional intention to exclude microorganisms from the scope of the patent laws.

III. ARGUMENT

A. What This Case Does Not Involve

1. The issues raised in *Chakrabarty* do not involve the patenting of phenomena of nature or the like

There have been many cases decided by this Court in which the issue presented involved the unpatentability of phenomena of nature and scientific principles in one form or another. Notable among these are *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1930), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), and *Parker v. Flook*, 437 U.S. 584 (1978). *Chakrabarty* is not such a case. Neither Petitioner nor PBC seriously contends that this case involves a product of nature.¹² Indeed, Petitioner expressly concedes that the *Chakrabarty* microorganism is *not* a product of nature (Pet. Brief at 33, n.39). An assertion that the invention involved was a product

¹² *Amicus* PBC half-heartedly contends at page 13, note 12 of its brief, that all forms of life are the "epitomy of laws of nature," which are allegedly unpatentable under *Flook*. Manifestly, living organisms no more epitomize the laws of nature than do other forms of matter in that all things, animate or inanimate, operate and interact only in accordance with the laws of nature. Even PBC does not contend that the claimed *Chakrabarty* invention is a law of nature, nor can it assert that it is a "product of nature" for reasons noted hereinafter.

Similarly, Petitioner's contention at page 23, n. 26 of its brief that, on the authority of *Flook*, living organisms are not the kind of discovery that the patent statute was designed to protect, is not based on an assertion that the claimed invention here in issue is a natural law or phenomenon. Indeed, the government's assertion is stated to be wholly independent of the scope of the patent claims presented. Rather, the contention is plainly seen to be part and parcel of Petitioner's assertion that implicit in various acts of Congress is the intention not to include living things within the general patent laws. This issue is addressed in detail in Section D, *infra*.

of nature was abandoned by the Patent and Trademark Office (PTO) Board of Appeals in *Chakrabarty*,¹³ was expressly rejected by the CCPA majority¹⁴ and need not be resurrected before this Court.

Moreover, the prior decisions of this Court clearly indicate that the *Chakrabarty* invention is *not* unpatentable as a product or phenomenon of nature. In *American Fruit*, a borax-impregnated orange was held unpatentable as a product of nature because borax impregnation did not produce an article having "a new or distinctive form, quality, or property." 283 U.S. at 11-12. In *Funk*, this Court held a mixture of non-inhibitive strains of bacteria unpatentable because the combination produced neither "new bacteria" nor an "enlargement of the range of their utility." 333 U.S. at 131. One must strain to deny that the normal meaning of the quoted passages from *American Fruit* and *Funk* would militate in favor of the patentability of the totally new, modified microorganism of *Chakrabarty*.¹⁵

¹³ This fact was noted in the CCPA's original *Chakrabarty* opinion, 571 F.2d at 42.

¹⁴ 596 F.2d at 973.

¹⁵ By way of further example, the CCPA majority noted that the naturally-occurring *Bergy* organism was quite useless before it was converted into the claimed biologically pure culture, 596 F.2d at 972, in contrast to the situation in *American Fruit* where both the starting material and the end product was an orange—just as edible and tasty before as after borax impregnation. The advance from uselessness to usefulness would appear to be the type of new or distinctive quality or property envisioned by *American Fruit* or the "enlargement of utility" contemplated by *Funk* as the indicium of an article of manufacture. Indeed, this is precisely the rationale of lower federal court decisions rendered after *Funk* and *American Fruit*. See, e.g., *Merek & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156 (4th Cir. 1958),

2. Whether or not the technology of genetic engineering is in the public interest should have no impact on the outcome of this case

a. *There is no doubt that granting patents on living organisms will promote the progress of the useful arts*

The constitutional mandate of the patent system is to promote the progress of the useful arts. There is virtual unanimity of opinion that genetic engineering technologies will greatly advance the state of numerous and varied technological arts including the pharmaceutical, energy and agricultural industries. There is also virtual unanimity of opinion that the availability of patent protection will, as it has in the pharmaceutical industry, promote research and development in genetic engineering technologies. Indeed, the brief of *Amicus* PBC, one of genetic engineering's most vocal critics, is replete with concessions that the issuance of patents in this area will perform the function intended by the framers of the Constitution and the

holding purified vitamin B₁₂ to be a new and useful composition rather than a product of nature.

The *Merck* approach has well served to promote the progress of the useful arts, particularly in the pharmaceutical technologies, and was earlier invoked to uphold the patentability of such useful materials as purified adrenalin and purified aspirin. *See* *Parke-Davis & Co. v. H. K. Mulford & Co.*, 196 F. 496 (2d Cir. 1912), affirming in pertinent part the district court's decision authored by Judge Learned Hand, 189 F. 95 (S.D.N.Y. 1911), and *Keuhsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir.), *cert. denied*, 220 U.S. 622 (1910).

drafters of the patent statutes.¹⁶ PBC is not alone in this assessment.¹⁷

¹⁶ Exemplary are the following:

Most financial and scientific observers concur that during the coming two decades, genetic engineering technologies will have a profit potential and social impact akin to the development of transistors and computers during the past 20 years. [PBC Brief at 2.] . . . Such a ruling [affirmance of the lower court decision herein] would significantly contribute to the profit potential of the genetic industry, thus generating a greater momentum in research and development of genetic engineering technologies. This, in turn, will lead to the rapid proliferation of genetic techniques in the areas of energy, agriculture, medicine, industrial processes and many other aspects of the nation's economic life. [PBC Brief at p. 3.] . . . [T]he flurry of research and development such patents will generate within the budding industry of genetic engineering are not in the public interest. [PBC Brief at 14.] . . . [G]ranting life form patents . . . will encourage industry to more rapidly develop genetic technologies. [PBC Brief at 17.] . . . [T]he granting of patents is sure to escalate the drive toward commercial application. [PBC Brief at 21.]

¹⁷ The final report on patent policy of President Carter's Advisory Committee on Industrial Innovation stated in reference to new life forms: "The availability of patents in this instance is certainly a stimulus to innovation, just as in the pharmaceutical fields, and seems justified for that reason." *Industrial Advisory Subcommittee Report on Patent Policy* in Advisory Committee on Industrial Innovation Final Report 145 (1979) [hereinafter cited as *Report on Patent Policy*] at 159. The report further states: "Unhindered by the threat of piracy, there will be stronger incentives to invest money in new and useful technology under the protection of the patent system." *Id.* In the same vein, the Director of the National Institutes of Health has stated: "The argument that commercial development based on patent protection has or will assure maximum benefits of these inventions to the public applies as well to the putative benefits of recombinant DNA inventions." Frederickson, *The Patenting Of Recombinant DNA Research Inventions Developed Under DHEW Support: An Analysis* by the Director, National Institutes of Health (November 1977) at 16. Indeed, National Institute of Medical Sciences head Ruth Kirschstein, testifying at a House Health, Education and Welfare Appropriation Subcommittee Budget Hearing on March 7, 1978,

It follows that genetic engineering research and development is precisely the type of technological innovation which the patent system was intended to promote and that the issuance of patents in this area will have precisely that effect. The degree to which this technology should be otherwise regulated is an issue wholly independent of the patentability question, as will be pointed out in greater detail in ensuing sections of this brief.

b. The absence of patents on living organisms will not preclude research or commercial exploitation in areas such as genetic engineering absent legislation by Congress, and will only limit public disclosure

From the inception of the patent system, patents have been regarded as performing the dual function of providing an incentive for technological innovation and providing a mechanism for early and widespread dissemination of technical information.¹⁸ Where patents are of doubtful validity or are unavailable, investors seek to minimize the not insubstantial risks of commercialization of new technologies by resort to trade secret protection. *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974). This is precisely the effect that the present uncertainty over the patentability of novel microorganisms is having in this burgeoning industry.

predicted that private industry will increase recombinant DNA research in the wake of the then recent CCPA ruling allowing new life forms to be patented. 21 The Blue Sheet, No. 10, RN-4 (March 8, 1978).

¹⁸ The White House Fact Sheet on the President's Industrial Innovation Initiatives issued October 31, 1979.

As recently reported in Newsweek, scientists-turned-entrepreneurs sometimes refuse to share their theories.¹⁹ An industry representative recently quoted in Business Week stated: "You keep your proprietary strains under lock and key."²⁰ The *Report on Patent Policy* notes that an argument favoring patenting new, useful and unobvious life forms "is that it provides an alternative to the less desirable avenue of trade secrets Maintenance of trade secrets also tends to stifle the free exchange of technology and hinders the progress of science by postponing the benefits to mankind of these technologies."²¹

The arbitrary exclusion of genetic engineering inventions from the patent system will not prevent the problems associated with continuing research, development and commercialization cited by PBC and Petitioner as militating in favor of that result. The only result of such exclusion will be that the public will suffer the further indignity of being subjected to potential risk from technology which is largely secret.

¹⁹ Newsweek quoted Stanford biochemist Paul Berg as follows: "No longer do you have this free flow of ideas. You go to scientific meetings and people whisper to each other about their company's products. It's like a secret society." Begley et al., *supra* note 5, at 53.

²⁰ Business Week, *supra* note 3, at 172.

²¹ *Report on Patent Policy*, *supra* note 17, at 159. Similarly, the Director of the National Institutes of Health observed: "Commentators from industry stated that patents expedite the disclosure of research results. Several noted that lack of patents would discourage the free flow of information because industry would seek to protect innovations through trade secrets." Fredrickson, *supra* note 17, at 6. The Director concluded: "There are no compelling economic, social, or moral reasons to distinguish these [recombinant DNA] inventions from others involving biological substances or processes that have been patented. . . ." *Id.* at 16.

Moreover, even if patents on new microorganisms *per se* are to be denied, there remains the concededly less desirable prospect that process patents can be obtained for some aspects of developing genetic engineering technologies.²² Indeed, as noted by the majority below, Chakrabarty's claims to a process for transferring plasmids and to an inoculated medium for the degradation of hydrocarbons have been allowed. 596 F.2d at 970-71. However, the relative ineffectiveness of these alternative forms of claims vis-a-vis claims to the basic product *per se* in protecting chemical and pharmaceutical inventions has long been recognized in the chemical patent law.²³ With this practical limitation in mind, it is seen that the arbitrary limitation of patents on novel microorganisms to claims other than those to the organism *per se* would have the wholly unsatisfactory effect of neither stopping innovation in the area nor fully encouraging its development and public disclosure. As noted at page 159 of the *Report on Patent Policy*: "If the progress of science is in the national interest, the term manufacture should be construed broadly, and patentability afforded to the useful bacteria resulting only from the efforts of man."

The foregoing economic realities merely serve to demonstrate and accentuate the legal characteristics of the patent grant. The grant, by its own terms, is simply the right to exclude others from practicing the invention. 35 U.S.C. § 154. It conveys no absolute right to the patentee to use the invention. *Application of Hartop*, 311 F.2d 249, 263 (C.C.P.A. 1962). Thus, as

²² Tullis, *supra* note 4, at 7.

²³ See, e.g., *Eli Lilly & Co. v. Generix Drug Sales, Inc.*, 460 F.2d 1096, 1103 (5th Cir. 1972); *Application of Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963).

is now the case with drugs, the patenting of a new microorganism will carry with it no right to commercialize that microorganism except as otherwise permitted by extant regulatory strictures.

c. The "sky-is-falling" arguments made against the patenting of living organisms could have been made against a multitude of inanimate technologies which have contributed heavily to this country's progress

Amicus PBC, and to a lesser extent Petitioner, liberally engage in what has been called "the doomsday scenarios of 'creative pessimism.'"²⁴ PBC is concerned with the lack of proven safety of genetic engineering techniques and seeks to impose on the Patent and Trademark Office the obligation to protect the public interest in this regard. However, as will soon be made apparent, controversiality has absolutely nothing to do with patentability. There are many technologies whose promotion is unquestionably in the public interest notwithstanding the presence of some degree of controversiality or risk in their practice. In 1977, nearly 5,000 people in the United States died of poisoning from exposure to chemical substances varying from antibiotics to petroleum products, yet PBC does not suggest that patents should not be granted on these concededly valuable materials. Also in 1977, 1,643 people died in air and space transportation accidents, yet PBC does not suggest that invention in this area should be unpatentable. Forty-nine thousand five hundred and ten people died in motor vehicle accidents in 1977, yet innovation in the area of automobile transportation is a high priority in

²⁴ Grobstein, *The Recombinant-DNA Debate*, in *Recombinant DNA* 131 (Scientific American, Inc. 1978) at 137.

energy conservation.²⁵ In short, arguments such as those here advanced by Petitioner and PBC predicated upon predicted calamities could have been advanced with equal force to arrest the development of any number of technologies, the overall social and economic value of which are now beyond question.

This point has not gone unnoticed in the genetic engineering debate. Grobstein notes that DNA techniques would not be the first technology to have potentially malevolent applications. "Explosives have such applications, but society does not completely ban them; it takes prudent precautions against their misuse."²⁶ Dr. J. D. Watson, Nobel laureate and codiscoverer of the structure of DNA, has noted:²⁷

Compared to almost any other object which starts with the letter D, DNA is very safe indeed. Far better to worry about daggers, or dynamite, or dogs, or dieldrin, or dioxin, or drunken drivers, than to draw up Rube Goldberg schemes on how our laboratory-made DNA will lead to the extinction of the human race.

It is for the Legislative and Executive Branches of government, not the Judicial Branch, to make the policy decisions with respect to the prudent precautions to be taken against the misuse of genetic engineering technologies. While the exact parameters of any regulatory scheme which may grow to surround these new technologies are presently unclear, it is presently clear

²⁵ National Safety Council, *Accident Facts 1979 Edition* (1979).

²⁶ Grobstein, *supra* note 24, at 140.

²⁷ Watson, *The Nobelist vs. the Film Star*, *The Washington Post*, May 14, 1978, at D1-2.

that the patent laws are not now and should not be part of that regulatory scheme.²⁸

As a practical matter, PBC has exaggerated the potential biohazards of genetic engineering technology. On June 23, 1976, in response to widespread debate on many of the issues raised by PBC and Petitioner, the NIH released guidelines to govern the conduct of NIH-supported research on recombinant DNA molecules.²⁹ In December 1978, NIH announced new, relaxed regulations in this area as a result of the failure of experiments designed to assess the potential hazards of DNA to demonstrate significant danger.³⁰ Indeed, a recent report in the press concerning worries cited by PBC and Petitioner was accompanied by the editorial comments that "those worries have eased" and that "much of the fear and controversy surrounding recombinant DNA research has dissipated."³¹

²⁸ A direct and compelling analogy is provided by the relationship between the patent laws and government regulation in the area of drugs. In *Hartop*, the CCPA rejected the notion that the Patent and Trademark Office was obliged to insure the safety and efficacy of patented drugs, noting: "The primary public duty, which the Patent Office is charged with performing under 35 U.S.C. §§ 101, 102 and 103, is to issue patents on applications which meet the statutory requirements." 311 F.2d at 261. Protection of the public from the use of unsafe and ineffective drugs is the responsibility of the Food and Drug Administration, not the Patent and Trademark Office. *Application of Anthony*, 414 F.2d 1383, 1395 (C.C.P.A. 1969).

²⁹ These guidelines specified varying degrees of containment procedures based upon the perceived degree of risk attending particular types of experimentation. See, e.g., Grobstein, *supra* note 24, at 141.

³⁰ *Business Week*, *supra* note 3, at 164.

³¹ *Business Week*, *supra* note 3, at 160, 164. See also Vossius, *Patentable Invention in the Field of Genetic Manipulations*, 1979 GRUR 579.

The conclusion is compelled that, while risk attends development of genetic engineering technologies, as it does development of many technologies, that risk is not as substantial as initially thought and certainly does not warrant rejection of the entire technology. In this regard, Nobel laureate J. D. Watson has described his own involvement in sounding the recombinant-DNA alarm as that of a "jackass" and has publicly stated his willingness to "go to jail" to "atone for the harm I've caused to others."³²

Much of PBC's rhetoric is a veiled policy argument that a technology conceded to be capable of widespread beneficial application should, nonetheless, be excluded from the protection of the patent system in vindication of a perceived social or ethical need to regard "aliveness" with an appropriate degree of awe and respect. A valuable lesson in this regard may be learned from the early experience with organic chemistry in which the very name of the field can be traced to the belief of Berzelius in 1807 that organic compounds could arise only through the operation of some "vital force" within the living cell.³³ While Berzelius' belief has since been shown to be unfounded, had that belief stood as a bar to patentability of inventions in

³² *Recombinant DNA and Genetic Experimentation* (Morgan and Whelan ed. 1979) at 236. Watson has stated his belief that DNA research is "much safer than many categories of work with disease-causing agents that the microbiologists have been carrying out for decades without significant harm to themselves, much less the public at large." Watson, *1978 Annual Report of Cold Spring Harbor Laboratory* (1978) at 6. See also *DNA Folly Continues*, *The New Republic*, January 13, 1979, at 12.

³³ See Fieser and Fieser, *Organic Chemistry* 3 (3d ed. 1956).

the area of organic chemistry, the development of that extremely useful art would have been greatly impeded.

If, because of overriding social or ethical questions such as concern for the public safety, national security, or public morals, the policy-making bodies of our government conclude that it is not in the public interest to grant patents in an area of the useful arts, it is incumbent upon those bodies, as it has been in the past, to exclude legislatively that technology from the scope of patent protection. Congress clearly did so in 1946 and 1954 by excluding certain innovations in the field of atomic energy from the scope of the patent laws.³⁴ The Congress was asked to act similarly in 1902 with respect to medical inventions but refused to do so.³⁵ It is manifestly more sound for Congress to act in those few areas where the patenting of new technologies will present social problems than to require the progenitor of every technological innovation to beseech Congress to enumerate specifically his technology in the statutes of the United States. Several foreign countries have enacted such exclusionary legislation respecting the patentability of higher life forms. The

³⁴ On August 1, 1946, Congress enacted the Atomic Energy Act of 1946, 60 Stat. 768, which excluded the production of fissionable material and the military utilization of atomic energy from the scope of the patent laws. On August 30, 1954, Congress enacted the Atomic Energy Act of 1954, 68 Stat. 943, relaxing but not eliminating the proscriptions of the 1946 Act.

³⁵ H.R. 12451, 57th Cong., March 12, 1902, *A Bill Amending the Statutes Relating to Patents, Relieving Medical and Dental Practitioners from Unjust Burdens Imposed by Patentees Holding Patents Concerning Methods and Devices for Treating Human Disease, Ailments, and Disabilities*.

new patent laws of Great Britain and West Germany are examples.³⁶

3. The potential patenting of higher forms of life is not before this Court in this case and need not be decided in order to resolve the issues presented by the Chakrabarty invention

The essence of the argument advanced by *Amicus* PBC is that if patents are allowed on microorganisms, it will be impossible to "draw the line" between lower and higher forms of life up to and including human clones. This case, being one of first impression, requires not the drawing of any line but merely the determination of whether a man-made microorganism which is new, useful and nonobvious must be excluded from patent protection merely because it is "alive." The judiciary does not usually draw lines prospectively, but instead decides concrete, present controversies. When a concrete controversy presenting more difficult patentability questions is presented, a line may have to be drawn, and that decision may not be an easy one to reach. However, the fact that a controversy is difficult to decide is no reason not to decide it.

This Court has in the past grappled with extraordinarily difficult legal controversies, many involving the mystical qualities of life here argued by PBC, and has, where necessary, drawn difficult lines. A classic example is this Court's decision in *Roe v. Wade*, 410 U.S. 113 (1973), where the right of a woman and her physician to terminate a pregnancy during the first trimester was sustained. This Court wisely declined

³⁶ It is to be noted that these foreign laws did not so exclude microorganism inventions and that microorganisms *per se* remain patentable in such countries. See § 3, *infra*.

to base that legal decision on the widely varying philosophical and theological views urged upon it as to when human life began, and instead based its decision on a more practical analysis of the public and private interests involved. Similar analysis is called for in the instant case.

The all-or-nothing argument of Petitioner and PBC is unsound for several practical reasons. In the first place, the patentability question will only be presented with respect to organisms which otherwise meet the existing statutory requirements for patentability. In this regard, it has long been recognized that the disclosure requirements now embodied in 35 U.S.C. § 112 are so stringent as to preclude as a practical matter the preparation of a complying description for even an asexually reproduced complex organism such as a rose. See *Application of LeGrice*, 301 F.2d 929 (C.C.P.A. 1962). Thus, except to the extent that certain complex plants are exempted from the disclosure requirement of 35 U.S.C. § 112 by special legislation, as they are under 35 U.S.C. § 162,³⁷ those organisms cannot be the subjects of valid United States patents. Petitioner seemingly concedes that the disclosure requirements will present insurmountable obstacles to the patenting of higher forms of life by noting: "[T]he reproductive ability of living things, and the small likelihood that even the most exact description of the method by which the originator developed his claimed invention will

³⁷ 35 U.S.C. § 162 provides in pertinent part:

No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.

This provision was part of the Plant Patent Act of 1930, to be discussed, *infra*.

permit its duplication, mean that living things do not fit easily within the general patent statute." Pet. Brief at 16, n.14.

With respect to a very narrow class of living inventions, namely microorganisms, mechanisms have been developed and judicially sanctioned for complying with the exacting disclosure requirements of the general patent law. *Application of Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970), sanctioned the placement of a novel microorganism employed in a microbiological invention in a national depository coupled with reference to the location of that deposit in the patent application as a means for complying with the requirements of § 112. Manifestly, unlike microorganisms which can be continuously cultured, higher forms of life present substantial problems in terms of indefinite maintenance on deposit and identical reproduction from the deposited specimen. Thus, there is little danger that issues involving the patentability of higher forms of life will arise in the absence of Congressional action akin to the 1930 Plant Patent Act reducing the disclosure requirements for these inventions.

Other sections of the existing patent law may also impede patenting of some of the more bizarre examples cited by PBC. For example, it is not inconceivable that a clone, an exact genetic duplicate of an existing organism, will be regarded as unpatentable for failure to comply with the novelty requirements expressed in the patent laws.

The fears of PBC are greatly overstated.

From the foregoing, it is apparent that, if a line must be drawn, it may easily be drawn between the mindless, soulless microorganism involved in *Chak-*

rabarty (as well as *Bergy*) and higher forms of life. As noted by the CCPA majority below, microorganisms such as that are more akin to inanimate tools of chemistry than they are to horses, honey bees and the like. Indeed, these inventions have recently been characterized as "Factories Too Tiny to See."³⁸

There seems to be technical support for such a distinction. For example, it has been noted that "[m]icro-organisms can be distinguished from plants and animals by their unicellularity or, in the case of multicellular forms, by their low level of tissue differentiation,"³⁹ and this distinction has been adopted in the patent laws of various European countries.⁴⁰

³⁸ Mathews, *Factories Too Tiny to See*, The Washington Post, January 23, 1980, at A-23.

³⁹ Byrne, *Patents on Life*, EIPR November 1979, 297 at 299. See also Grobstein, *supra* note 24, at 137 distinguishing between prokaryotic organisms such as bacteria and eukaryotic organisms such as man on the basis of the location and complexity of chromosomes.

⁴⁰ Byrne, *supra* note 39, at 299. The structure of the British Patents Act 1977 is generally to authorize issuance of patents for any invention which is new, inventive and capable of industrial application and, in subsequent sections of the act, to exclude from the general class of inventions patentable those which present particular social problems. Section 1(3) is such a section, and reads in pertinent part:

(3) A patent shall not be granted—

(b) For any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.

The British law represents enabling legislation carrying into effect the provisions of Article 53(b) of the European Patent Convention, which has been ratified by at least ten European countries, and in accordance with which microorganisms themselves but not higher life forms are patentable. See Vossius, *Patent Protection for Biological Inventions—Review of Recent Case Law in EEC Countries*, EIPR October 1979, 278.

European governments are actively promoting genetic engineering research and some U.S. investment and research activity is moving overseas. The potential exists, therefore, for the U.S. to lose its hold on this technology, and this potential should not be lightly dismissed in considering the practical impact of the issue presented by this case."

4. **Petitioner's argument based on the practical success or failure of the patent acts covering plants is irrelevant to the issues in this case and is based on faulty factual assumptions**

Amicus PBC argues by analogy that permitting the patenting of life forms will have the same deleterious effect on the animal gene pool that the various plant patent laws are alleged to have had on the plant gene pool. In this regard, PBC states (1) that a direct result of plant patent legislation has been the elimination of thousands of useful varieties of plants from the planetary gene pool; (2) that as patentable plants have been widely propagated, nonpatentable varieties have been eliminated resulting in disease and pest-susceptible crops; and (3) that plant patents have made plant breeding such a lucrative endeavor that ownership of the world's basic food supply is increasingly being concentrated within a small number of large, multinational corporations. PBC Brief at 6-13.

Initially, it must be noted that there is no comparison between the magnitude of the plant gene pool and that of the microorganism pool. Plants, by their size, complexity of structure and ability to grow only in

⁴¹ *Business Week*, *supra* note 3, at 164. See also D. Dickson, *Recombinant DNA Research: Private Actions Raise Public Eyebrows*, 278 *Nature*, 494, 495 (April 1979), reporting the willingness of certain industrial elements to locate in the country offering the most acceptable environment for research.

various zones, are finite in number. Prokaryotes (unicellular microorganisms), by comparison, are simple in structure and reproduce everywhere on this earth in virtually infinite numbers. Accordingly, it is reasonable to assume that genetic engineering research will not reduce the gene pool relating to microorganisms but, if anything, will add to it.

Moreover, the PBC argument is based on faulty factual assumptions. Although germplasm (genetic material) *conservation* is a relatively recent phenomenon, the *loss* of germplasm is something that has been occurring ever since man first cultivated crops. Today, scientists aware of the problem have set up germplasm preservation centers.⁴² While it is acknowledged that a problem exists in conserving all the germplasm extant on the planet, this is a problem that precedes by hundreds of years the passage of the plant protection laws and which, with the attention generated by the passage of those laws, has been recognized and is being rectified. Surely, a dynamic plant-breeding industry—in both the private and public sectors—which has as one of its functions the task of maintaining genetic stocks, is one of the best safeguards against "genetic wipeout."

With regard to the PBC allegation of widespread monoculturing and the resultant disease and pest-

⁴² The U.S.D.A. maintains such a center at Fort Collins, Colorado, for preservation and distribution of samples of all seeds sent to the Patent and Trademark Office and to the U.S.D.A. The U.S.D.A. also collects wild seeds and maintains regional preservation centers in seven United States cities. There are also seven International Research Centers acting as repositories for seed which is made freely available to any country and to any breeder. J. M. Poehlman, *Breeding Field Crops*, (2d ed. 1979) at 109-112.

susceptible crops, it is true that there was an extensive corn blight in the U.S. in 1970, resulting in part from genetic limitations of a widely used corn seed. However, the very seed companies which supplied the corn seed in 1970 were able to obtain germplasm from the regional centers and were able to correct the deficiency by the planting of the 1971 crop.⁴³

With respect to the effect of prior legislation on the major food crops, it must be remembered that the Plant Patent Act of 1930 applies only to asexually reproduced plants, which include very few food crops. Thus, although beans, peas and lettuce theoretically might be subject to patents, they in fact are not. It is only since 1970 that sexually reproduced plants, which include most major food crop plants, have been certified. The effect of the 1970 Act, far from reducing the number of varieties available to the American public, has increased them.⁴⁴ The result of the passage of the 1970 law has been to foster technology and to increase the number of hearty varieties of crop seed available to the American farmer.⁴⁵

⁴³ It should also be noted that the first certificates under the Plant Variety Protection Act were issued in 1972, so the effects of that act cannot be said to have contributed to the corn blight.

⁴⁴ For example, there were as many new varieties of wheat developed in the seven years following passage of the Plant Variety Protection Act as had been developed in the previous seventeen years. *Hearings on H.R. 2844 Before the House Agriculture Subcommittee on Department Investigations, Oversight and Research*, July 19, 1979 (Statement of Commissioner Leese, Office of Plant Variety Protection). Similarly, while there were six companies doing work with soybean breeding before 1970 there are presently 25. White, *Plant Variety Protection Update*, Proceedings of the Sixth Soybean Seed Research Conference (1976) at 33, 37. See also Poehlman, *supra* note 42, at 448-49.

⁴⁵ This is exactly the result foreseen by the House Agriculture Committee in its report on the Plant Variety Protection Act. The

Finally, *Amicus* PBC's contention that the Plant Variety Protection Act has lead to a monopolization of the world's germplasm through patents is similarly mistaken. In the decade since the passage of that Act, the number of seed companies, especially in soybeans, wheat and cereal grains has increased.⁴⁶ Some acquisition of small companies by petrochemical companies, multinational and otherwise, has taken place, and these companies may own a large percentage of issued plant patents, but this by no means proves control of any given crop's germplasm.⁴⁷ The mere number of patents

Committee noted that the seed industry in Western Europe and especially England, far from withering, showed "signs of great new vitality" after passage of the patent act. The House Report further stated:

Legal protection for plant varieties will give American farmers the choice of more and better varieties. . . . Soybeans provide a good example of a crop that could and would be more productive as a result of the more and better varieties which would be available as a result of legal protection for plant varieties. Other major U.S. crops, like cotton, wheat, barley, oats, and rice, for example, now largely ignored by the private researchers, would almost certainly benefit greatly from the impact of a competitive, private plant breeding effort. . . .

H.Rep. No. 91-1605, 91st Cong., 2d Sess. (1970).

⁴⁶ *Hearings on H.R. 2844, supra* note 44 (Statement of Harold Loden, Executive Director of the American Seed Trade Association). Membership in ASTA has increased 25% in the last five years. See also statement of Leese, *supra* note 44.

⁴⁷ For example, *Amicus* PBC cites Ciba-Geigy as one of those companies controlling plant patents through Funk Seeds International and Stewart Seeds, and hence the germplasm of the plants covered. In reality, Funk has only one certificate and that is on a soybean variety not currently on the market and not likely to be marketed. Stewart Seeds is a Canadian seed company not within the control of Ciba-Geigy (U.S.).

In a similar vein, Monsanto, another giant cited by *Amicus* PBC as a monopolizer of plant patents has no seed companies.

owned by individual companies or groups of companies proves nothing with respect to market control. In all areas of technological innovation, the largest numbers of patents are usually held by corporate entities, and there is no way to determine from the numbers of patents held which are the important and controlling patents."

In the seed field, ownership of plant certificates does not dictate control of the sale of seed. In this regard, it is noted that U.S. seed companies have traditionally been small, family firms without the capital to invest in long-term research projects leading to new varieties. Since the seeds sold by these companies are not usually certified, there is no way to account for their share of the market.

Since 1970, 980 applications on 57 distinct crops have been received by the Plant Variety Protection Office. Of these, only 197, or roughly 1/5, were from the six largest U.S. seed companies. One hundred seven applications were from experimental stations and the rest, 676, were from private breeders of all sizes." This diversity belies the contention of *Amicus* PBC that plant certification has encouraged undue concentration

Farmer's Hybrid, cited in Cary Fowler's testimony (PBC Brief at 12, note 10), is a pig hybridization company.

⁴⁸ *Report on Patent Policy*, *supra* note 17, at 152 n.13, 166.

⁴⁹ See Statement of Leese, *supra* note 44. A perusal of the Indices to the Official Journal of the Plant Variety Protection Office supports this diversity. In 1978, for example, 90 certificates were issued to more than 50 seed companies. Twenty certificates were issued on beans, peas and lettuce, the crops named by the PBC as "controlled," to eleven different companies, including an individual seedsman.

of ownership of seed companies to the detriment of the public.

B. The Holding Below in *Chakrabarty* Is Totally Compatible With an Almost 200-Year Old Statutory Scheme and the Historical Application of the Patent Laws

1. Contrary to *Deepsouth*, this is not an extension of patent laws

Petitioner relies heavily on this Court's statement in *Flook* that it "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress," 437 U.S. at 596, which in turn relied on *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972). In its opinion, 596 F.2d at 966-967, the CCPA easily distinguished *Deepsouth* on the basis of the legal issue involved therein (infringement), the language of 35 U.S.C. § 271 and the large body of judicial precedent construing Section 271, the latter having been characterized by this Court as "unassailable absent congressional recasting of the statute." 406 U.S. at 528. Since whether subject matter is excluded from Section 101 of the patent statute merely by virtue of being "alive" is, according to both Petitioner (Pet. Brief at 13) and the CCPA, an issue of "first impression," there is no "unassailable" judicial construction of the statute which one must look to Congress to overrule. Accordingly, the issue in this case is not whether there is to be *extension* of a statutory privilege of the sort contemplated in *Deepsouth*, but instead whether the *Chakrabarty* invention qualifies for an *existing* statutory privilege.

2. The statutory scheme since 1790 has contemplated patenting of new and unforeseen technologies

Petitioner seeks to glean support from *Flook* for the proposition that the impetus for extension of the patent laws to new technologies must come from Congress. Despite the sharp differences reflected in the majority and dissenting opinions below, the CCPA *unanimously* rejected this proposition. 596 F.2d at 973. Indeed, any such theory would be wholly inconsistent with the statutory scheme and the historical application of the patent laws.

Scarcely two and one-half years after the signing of the Constitution, the first Congress enacted the Patent Act of 1790.⁵⁰ Section 1 of the Act provided for patents to be issued to persons who have invented or discovered "any useful art, manufacture, engine machine, or device, or any improvement therein not before known or used" Section 2 of the Act of 1790 required further that the grantee deliver a written specification containing a description of the invention which would enable one "skilled in the art of manufacture, whereof it is a branch, *or wherewith it may be nearest connected* [emphasis added]" to make and use the invention. One could not ask for a clearer manifestation of the perception of the first Congress that the patent laws were intended to encompass innovation in areas not pertaining to *existing* arts than the plain meaning of the first description requirement. Moreover, implicit in Section 1 of the Act is the presumption that "any useful art," for example, should include more than mere improvements on existing arts, since the additional provision for "improvement[s]"

⁵⁰ 1 Stat. 109, April 10, 1790.

therein" would otherwise be wholly superfluous. Upon construing Sections 1 and 2 of the Patent Act of 1790 together, the conclusion is compelled that the categories of patentable subject matter defined in that Act included altogether new and unforeseen technologies. Parallel statutory requirements survive to this day in 35 U.S.C. §§ 101 and 112.

3. The patent laws historically have been applied to new technologies as they developed, including those related to living organisms

That the patent laws historically have been extended to new technologies as they have developed is apparent from a chronological review. With respect to historical development of the statutory language, it is noted that the United States patent laws were amended shortly after enactment of the first patent act by the Patent Act of 1793.⁵¹ This Act provided for patents to be granted to persons who invented "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter" The disclosure requirements were carried over in Section 3 of the Act of 1793. The resemblance of these two sections to the present law is obvious, and this similarity prevailed through amendments to the substantive patent law which Congress had occasion to make in 1836, 1870, 1874, 1930, and 1952. The nature of the technological developments accepted within the patent system during the intervals between congressional reexamination of the statute belies any conclu-

⁵¹ 1 Stat. 318, February 21, 1793.

sion that new technologies were not regarded as falling within the statutory language.⁵²

Two examples serve to illustrate the point. In 1840, a patent was issued to Samuel Morse for an invention relating to "Telegraph Signs,"⁵³ and the validity of the first seven claims of that patent was upheld by this Court in the landmark case of *O'Reilly v. Morse*, 56 U.S. (15 How.) 61 (1853). Nearly 60 years later, in 1897, Guglielmo Marconi received a patent for "New and Useful Improvements in Transmitting Electric Impulses and Signals and in the Apparatus Thereof"⁵⁴—the forerunner of the radio. Congress itself has spoken on the lack of foreseeability of such new technologies in the legislative history of the Plant Patent Act of 1930, where it characterized telegraphic communication and radio communication as "matters beyond the wildest dreams of the framers of the Constitution."⁵⁵ One would think that statutory language which had allowed the issuance of the Morse and Marconi patents on telegraphy and radio, and which allowed this Court to sustain as a patentable invention Morse's telegraph when properly claimed, would be acknowledged as subsuming within its scope wholly unforeseen and new technologies in view of this express Congressional statement.

⁵² This point is developed extensively by counsel for *Amicus PMA* in Dunner et al., *The Patentability of Life Forms, New Technologies and Other Flocks of Nature*, 7 A.P.L.A. Quart. J. 190 (1979) at 198-203.

⁵³ U.S. Patent No. 1,647, issued June 20, 1840.

⁵⁴ U.S. Patent No. 586,193, issued July 13, 1897.

⁵⁵ S.Rep.No. 315, 71st Cong., 2d Sess. (1930) at 8.

Microorganisms have not been strangers to the patent system and actually formed the subject matter of a number of United States patents issued since the 1930's.⁵⁶ Indeed, in 1873, a patent was granted to Louis Pasteur for "Improvements in the Manufacture and Preservation of Beer and in the Treatment of Yeast and Wort, Together with Apparatus for the Same."⁵⁷ For purposes of our present inquiry, it is interesting to note that claim 2 of the Pasteur patent called for "Yeast, free from organic germs of disease, as an article of manufacture,"⁵⁸ or in other words, a biologically pure culture of a microorganism. Moreover, it was a microbiological invention which was considered by the Supreme Court in *Funk*.

From the foregoing, it is apparent that the patent statutes, in practical application, have throughout the

⁵⁶ Exemplary are the patents collected in Daus et al., *Microbiological Plant Patents*, 10 IDEA 87 (1966) and listed in the CCPA majority opinion, 596 F.2d at 985-86.

⁵⁷ U.S. Patent No. 141,072, issued July 22, 1873.

⁵⁸ Petitioner notes that a commentator in 1937 questioned the validity of this claim of the Pasteur patent. Federico, *Louis Pasteur's Patents*, 86 Science 327 (1937). It is noted that the authority cited for that position was *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1930), which, as pointed out in § A.1, *supra*, does nor bar the patentability of such purified microorganism cultures.

Petitioner, at pages 39-40 of its brief, also challenges the precedential value of the prior patents issued on microorganisms noted by the lower court, 596 F.2d 985-86. It is contended that the cited examples are "aberrant." It must be noted however, that the patents cataloged in the majority opinion are said to be typical and by no means exhaustive. Moreover, most of them were issued *after* and notwithstanding the publication of the foregoing remarks of P. J. Federico. Petitioner cites no evidence of aberration in the grants of these patents, which must be presumed to have been validly issued (35 U.S.C. § 282), other than Petitioner's present opinion on the patentability of microorganisms which finds no basis in published policy prior to the present controversy.

history of the system routinely been construed as covering technological innovation, both animate and inanimate, wholly unforeseen by the founding fathers in the 18th Century or even by legislators in 1952. Accordingly, there is no warrant for any construction of the *Flook* dictum relating to "new technologies" which would bar technological innovation from the subject matter susceptible of being patented simply because it is innovation not foreseen by the drafters of the Constitution or the various patent statutes.⁵⁹

4. Applying the patent laws to new and unforeseen technologies best achieves the constitutional purpose of promoting the useful arts

The constitutional purpose of the patent system is to promote the progress of the useful arts. If one believes in the patent system, one would want to use the patent grant as a tool to encourage invention and innovation whenever and wherever it appeared capable of achieving that purpose. Of course, where Congress or this Court has clearly spoken to the contrary, the patent option will be unavailable. But where neither has done so, which we submit is the case here, there is

⁵⁹ Notwithstanding the foregoing, Petitioner contends that the statutory terms "manufacture" and "composition of matter" are "obscure" and "hardly define themselves" and must be construed in light of remotely related legislation (Pet. Brief at 30). In point of fact, however, historical perspective shows the meaning of these terms to be quite clear, albeit very broad. Petitioner confuses breadth with indefiniteness. Simply stated, all manner of materials brought into existence by the hand of man have been regarded as manufactures, whether foreseeable or unforeseeable. It is noted in this regard that resort to legislative history, such as that of the Patent Act of 1930 so heavily relied upon by Petitioner, is unnecessary when the statutory language is unambiguous, as it is here in light of its historical application. *United States v. Oregon*, 366 U.S. 643, 648 (1961).

no reason to go out of the way to create artificial impediments to the patent-granting process. As Judge Markey so aptly stated in his original concurring opinion in *Chakrabarty*:⁶⁰

As with Fulton's steamboat "folly" and Bell's telephone "toy," new technologies have historically encountered resistance. But if our patent laws are to achieve their objective, extra-legal efforts to restrict wholly new technologies to the technological parameters of the past must be eschewed. Administrative difficulties, in finding and training Patent and Trademark Office examiners in new technologies, should not frustrate the constitutional and statutory intent of encouraging invention disclosures, whether those disclosures be in familiar arts or in areas on the forefront of science and technology.

C. Contrary to Petitioner's View, It Was Not the General Understanding Prior to the Decision Below That Legislation Was Needed if the Patent Laws Were to Be Applied to Microorganisms

Petitioner contends that the decision below was a departure from the general understanding that patent coverage was not available for microorganisms absent legislation (Pet. Brief at 13). Petitioner's argument in this regard is multi-faceted, relying on prior judicial precedent, pronouncements of the organized bar and statements of commentators.

It is stated that the only judicial pronouncements on the subject suggest living things are not themselves patentable. *Guaranty Trust Co. v. Union Solvents Corp.*, 54 F.2d 400 (D. Del. 1931), *aff'd*, 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933), and *Application of Mancy*, 499 F.2d 1289 (C.C.P.A. 1974)

⁶⁰ 571 F.2d at 44.

are cited by Petitioner in support of this proposition. Such reliance on these decisions is necessarily blunted by Petitioner's concession in the paragraph containing these citations that the question involved in this case "is an issue of first impression."

One of the reasons this is a case of first impression is that *Guaranty Trust*, in holding a microbiological process patentable, expressly demurred on the question of the patentability of bacteria per se: "Were the patent for bacteria per se, a different situation would be presented." 54 F.2d at 410. Similarly, there was an express reservation of decision on the issue here presented in *Mancy*: "[A]ppellants . . . would, we presume (without deciding), be unable to obtain such a [micro-organism] claim" 499 F.2d at 1294. The *Mancy* court's presumption was based on the not uncommon perception of such microorganisms being "products of nature," a point not at issue in this case.⁶¹

Petitioner also suggests, through citation of excerpts from reports of various bar associations, that the organized bar regarded legislation as necessary to bring microorganisms within the ambit of the existing patent law. Far from supporting Petitioner's theory,⁶² the

⁶¹ While Petitioner goes to great pains to demonstrate that what was involved in *Mancy* was in fact no more a product of nature than the purified microorganism of Bergy, the uncontroverted fact is that the *Mancy* court, rightly or wrongly, expressly presumed the microorganism there involved to be a product of nature.

⁶² For example, Resolution 22 of the American Bar Association Patent, Trademark and Copyright Law Section (ABA Pat. Sec.) passed in 1966, regardless of how entitled, stated support for the "application of the principles of the patent system to all . . . microorganisms." 1966 ABA Pat. Sec. Summary of Proceedings at 84, emphasis added. That "extension" of the patent laws is not necessarily entailed in such "application" of them to microbiology is manifest from the accompanying Report of Committee 108 on Patent System Policy Planning, where it is stated: "There

reports of the organized bar suggest the perception that microorganisms were patentable under existing law.

is no logical reason why asexually reproduced plants and microorganisms should be covered by patents as at present, where sexually reproduced ones are not covered by patents" 1966 ABA Pat. Sec. Committee Reports at 77, emphasis added.

The problems perceived in this area were problems of description, as demonstrated by Resolution 11 adopted by the full ABA in 1969 approving the deposit of novel microorganisms in public depositories as a means of complying with the disclosure requirements of the patent laws. This resolution was seen as eliminating uncertainty in the application of existing law to microorganisms: "The proposed legislation would take nothing away from the existing statute, 35 U.S.C. § 112, but rather would codify and settle Patent Office practice in this area." 1969 ABA Pat. Sec. Committee Reports, Report of Committee 101 on Patent Law Revision at 14. In this regard, the legislation supported by the ABA referred to at page 29, n.35 of Petitioner's brief as being "with respect to patent protection for micro-organisms" actually related to elimination of these description difficulties.

Microorganisms were also mentioned from time to time by various committees and subcommittees dealing with plant patent legislation. Exemplary is the Report of Subcommittee E of Committee 103 in the 1969 ABA Pat. Sec. Committee Reports quoted by Petitioner at page 14 of its brief. By the very terms of the Committee Report, the quoted remarks were speculative since the Committee had "not conducted a study in depth of the microbiological area with relation to patents." *Id.* at 123.

Petitioner also relies (Pet. Brief at 14, n.12) on a 1976 resolution of Committee 111, Plant Patents and Plant Variety Certificates, suggesting revision of existing plant patent provisions to include microorganisms. Petitioner fails, however, to note that the accompanying 1976 ABA Pat. Sec. Summary of Proceedings at 95 suggests that the provision "was removing a disability rather than creating a new right [emphasis added]."

In stark contradiction to the position urged by Petitioner, the very committee responsible for original Resolution 22 in 1966 saw no apparent inconsistency in 1978 in adopting Resolutions 30, 31 and 32 favoring construction of the existing patent laws so as to include microorganisms within their scope. 1978 ABA Pat. Sec. Summary of Proceedings at 64-67.

Petitioner's reliance on literature references to the desirability of additional legislation is also misplaced. Examination of the references cited at p. 15, n.13 of Petitioner's brief merely confirms the obvious—that legislation beyond the Plant Patent Act of 1930 would be required to allow patenting of various other kinds of *plants, animals and their products*. Nothing is said of microorganisms save the passing reference to "yeast" in Dienner, *Patents for Biological Specimens and Products*, 35 J. Pat. Off. Soc'y. 286, 290 (1953). That lone reference is in the context of an arguendo assumption that "national legislations could be construed *as they stand*, or amended as desired, to cover biological products and specimens [emphasis added]."

D. Congress Did Not Intend to Exclude Microorganisms From the Scope of 35 U.S.C. § 101

1. Petitioner's position that the Plant Patent Act and Plant Variety Protection Act preclude construction of 35 U.S.C. § 101 to cover microorganisms is based on fallacious assumptions and unduly expansive interpretations of the legislative history

Petitioner contends in essence that all living things are excluded from patentable subject matter under 35 U.S.C. § 101 because patents for certain kinds of *plants* have been the subject of subsequent legislation. Even this simple statement of Petitioner's position reveals two of its major flaws. In the first place, Petitioner consistently characterizes considered statements made in reference to specific "plants" or "animals" as supporting identical propositions with respect to the broader class of "living things."⁴³ Petitioner consist-

⁴³ Merely by way of example, Petitioner cites a remark of Representative Purnell relating to "new forms of *plant or animal* life (emphasis added)" at page 26 of its brief and extrapolates

ently engages in the patently fallacious syllogism that (1) certain plants and animals were unpatentable prior to 1930, (2) plants and animals are "living things" and, therefore, (3) all "living things" were accordingly unpatentable prior to 1930.

Plants, in the common sense of the word, were not patentable before 1930 because they could not be described with the particularity required by the patent statutes.⁴⁴ There was the parallel concern in 1930 that plants were unpatentable because they were "products of nature." The legislation in 1930 eliminated the dis-

it to a conclusion relating to "patentability for living things." That same conclusion is also said to be supported by a similarly unwarranted extrapolation of a remark of Representative Stafford relating to the unpatentability of "rare species of cattle or chickens." Moreover, at page 15, n.13 of its brief, Petitioner cites Glascock and Stringham, *Patent Soliciting and Examining* 591 (1934) and R. Allyn, *The First Plant Patents* 10 (1934) as examples of experts who thought that "without additional legislation no patents could issue for *living things*." In point of fact, however, Glascock and Stringham referred only to "plants" and "novel types of animal life" while the cited Allyn page merely suggests further encouragement for "animal breeders."

⁴⁴ In this regard, note *Application of LeGrice*, 301 F.2d 929, 944 (C.C.P.A. 1962), where the court noted: "[T]here is no possibility of producing the plant *from a disclosure* as 35 U.S.C. § 112 contemplates." The court went on to note: "The descriptions of the new roses in the instant publication [footnote deleted] . . . are incapable of placing these roses in the public domain by their descriptions when interpreted in the light of the knowledge now possessed by plant breeders." *Id.* Note also the following from Rossman, *The Preparation and Prosecution of Plant Patent Applications*, 17 J. Pat. Off. Soc'y. 632, 638 (1935):

It may be interesting to note that botanists long ago gave up the attempt to differentiate plants by verbal description and even drawings and photographs. They rely only upon actual examination of the plants. The patentability of a new distinct variety thus necessarily rests upon the possibility of so describing and illustrating it that it can be identified or distinguished from other closely related forms with reasonable accuracy.

closure impediment and clarified the "product of nature" point. It cannot seriously be contended that this clarifying legislation compels the conclusion that some other type of "living thing," *e.g.*, microorganisms, to which the description requirement and "product of nature" impediments are not applicable, would not have been patentable under existing law.

The second flaw in Petitioner's position is that it constitutes an *ex post facto* construction of statutory language dating back to 1793 on the basis of opinions expressed by Congress more than 150 years later. Such after-the-fact opinions are of little legal value even if clearly expressed, as they certainly are not in this case.

a. The Plant Patent Act and the Plant Variety Protection Act had nothing to do with microorganisms

As pointed out in *Application of Arzberger*, 112 F.2d 834 (C.C.P.A. 1940), which held that microorganisms were not intended by Congress to be patentable under the Plant Patent Act of 1930, while the scientific definition of plants at the time of the 1930 Act arguably may have included bacteria, the nonscientific common language definition surely did not. According to *Arzberger*, the word "bacteria" was not mentioned in the House and Senate reports accompanying the bills leading to the 1930 Act, confirming the view "that Congress, in the use of the word 'plant', was speaking 'in the common language of the people,' and did not use the word in its strict, scientific sense." 112 F.2d at 838.

In short, Congress, in enacting the Plant Patent Act of 1930 for the purpose of affording "agriculture so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given

industry," and in removing the "existing discrimination between plant developers and industrial inventors,"⁶⁵ was not suggesting or even remotely intimating that bacteria had not previously been covered by the patent laws, but only that "plants" in their commonly understood form were not so covered. Thus, the legislative history of the 1930 Act is, at best, neutral on the subject of the patentability of bacteria (microorganisms). Since Congress gave absolutely no thought to the patentability of bacteria, or whether or not they were covered by the existing patent laws, it can hardly be concluded that anything Congress did in 1930 bears on that issue.

Little more is added to the foregoing by the Plant Variety Protection Act. Petitioner notes that the subject matter for which Certificates of Plant Variety Protection can be issued specifically excludes bacteria and fungi. The legislative history of the Act is strangely silent on the reasons for the exclusion of bacteria and fungi. However, the protection intended is characterized in the Report of the House Agriculture Committee⁶⁶ as "similar" to the protection afforded asexually reproduced varieties through plant patents. As above noted, the manifest limitation of

⁶⁵ S. Rep. No. 315, 71st Cong., 2d Sess. (1930) at 1.

⁶⁶ H. Rep. No. 71-1605, 91st Cong. (1970). Petitioner, at pages 27-30 of its brief, makes much of the fact that Congress in 1970 regarded additional legislation as necessary to protect sexually reproduced plants. However, the impediments to the patenting of complex plant life, such as the inability to describe plants, apply to all such plants, not just the asexually reproduced plants for which the impediments were removed in 1930. Since the earlier legislation was restricted to asexually reproduced plants, there is no great significance to the subsequent passage of parallel legislation to convey the benefits of patent-type protection to the previously excluded class.

Congressional intention in enacting the Plant Patent Act to plants in the ordinary sense of the word had been judicially recognized for 30 years before passage of the Plant Variety Protection Act, and the express limitation of the latter to plants in the ordinary sense of the term can be regarded as nothing more than a desire to parallel the existing legislation. It does not, therefore, manifest any greater consideration by Congress of the issue presented by these cases than occurred in 1930.

b. The views of a subsequent Congress are of little value in determining the intent of a prior Congress.

As the majority opinion below aptly noted, the remarks of a subsequent Congress cannot safely be used to ascribe to a preceding Congress an intent which the latter did not itself state. 596 F.2d at 978.⁶⁷ Petitioner seeks to distinguish the situation in *Chakrabarty* by noting that the patent laws had been "codified" in 1952 so that yet a third Congress had spoken on the topic (Pet. Brief at 30-31).

Even if it were assumed that this third Congress tacitly endorsed all the remarks of the second Congress, an assumption not warranted by the cited legislative history, the net effect remains that of a later Congress opining on the intent of an earlier Congress—still a wholly unreliable indication as to the construction of the original act. Moreover, even if the 1952 codification represented adoption of the views of the

⁶⁷ Petitioner challenges (Pet. Brief at 30, n.36) the lower court's reliance on *United States v. Price*, 361 U.S. 304 (1960), as support for this proposition. Whatever else *Price* may stand for, it unequivocally states as an *independent* ground for decision: "Moreover, the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *Id.* at 313.

1930 Congress, those adopted views were no more compelling in 1952 than they were in 1930 for the reasons noted herein.

2. Collateral elements of the legislative history of the Plant Patent Act do not establish a Congressional intention to exclude microorganisms from the scope of the patent laws

Petitioner also relies on several other collateral elements of the Plant Patent Act legislative history, primarily a remark made by Secretary of Agriculture, Arthur M. Hyde, in a letter appended to the report of the Senate Committee on Patents,⁶⁸ wherein it is stated:

This purpose [to encourage improvement of some kinds of plants] is sought to be accomplished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inanimate nature.

The report to which the letter is appended twice quotes Secretary Hyde, once as to the desirability of the proposed legislation⁶⁹ to agriculture and the public and once for an assurance of cooperation between the Department of Agriculture and the Patent Office.⁷⁰ Accordingly, the Congress cannot be said to have either solicited Secretary Hyde's opinion as to the scope of

⁶⁸ Senate Report of the Committee on Patent accompanying the Plant Patent Act of 1930, S. Rep. No. 315, 71st Cong., 2d Sess. (1930). See also the discussion of remarks by several Congressmen cited by Petitioner (Pet. Brief at 26) at note 63, *supra* and accompanying text.

⁶⁹ *Senate Report, supra* note 68, at 3.

⁷⁰ *Senate Report, supra* note 68, at 5-6.

the existing patent law or adopted that opinion. The remark of Secretary Hyde in question is, therefore, no more reliable as an indication of Congressional intention than any other comment submitted to Congress before it acts.⁷¹ As noted in *United States v. Fairfield Gloves*, 558 F.2d 1023, 1027 (C.C.P.A. 1977), an opinion authored by Judge Miller, the lone dissenter below and a former U.S. Senator:

Statements made in briefs or in testimony presented at committee hearings cannot be considered as a guide to what Congress intended, since Congress has not delegated to organizations or individuals appearing before its committees the authority to construe a statute.

Accordingly, the quoted remark of Secretary Hyde is without legal effect.

3. There are several plausible explanations for the Plant Patent Act other than that urged by Petitioner

It is argued that there is no possible reason for the addition of language describing various kinds of plants to the categories of statutory subject matter in R.S. 4886 except that such plants were not encompassed within the existing language. However, there are at least two other plausible reasons,⁷² both of which find

⁷¹ Petitioner seeks to buttress the significance of Secretary Hyde's opinion as to the scope of existing patent law, a law which he was not charged with administering, by opining that Secretary Hyde must have had the "advice of expert patent counsel" (Pet. Brief at 26, n.28). Suffice it to say, the existence, content or reliability of any such advice does not appear from the legislative history and must be regarded as pure conjecture.

⁷² See, e.g., Gutttag, *Patentability of Microorganisms: Statutory Subject Matter and Other Living Things*, 13 U. Rich. L. Rev. 247, 263 (1979).

as much support in the legislative history as Petitioner's theory.

The first and most obvious reason for the amendment would be to declare the existence of rights whose existence might otherwise be subject to question. As noted in the CCPA majority opinion, 596 F.2d at 982, plants had been regarded as "products of nature," not resulting from the work of man, and thus not "inventions" within the meaning of the statute.⁷³ In enacting the Plant Patent Act, Congress took great pains to declare that certain works of plant originators were, in fact, "inventions" rather than "products of nature."⁷⁴ Since the pertinent statutory language—"[w]hoever invents or discovers"—was the same both before and after passage of the 1930 Act, extensive consideration by Congress of the "invention" issue is consistent with a desire to declare and clarify existing rights, viz., that certain plants were not products of nature and were thus subsumed within the statutory language relating to inventions even prior to the 1930 Act.⁷⁵

⁷³ See, e.g., *Ex parte Latimer*, 1889 Dec. Comm. Pat. 123 and *Thorne, Relation of Patent Law to Natural Products*, 6 J. Pat. Off. Soc'y. 23 (1923).

⁷⁴ *Senate Report*, *supra* note 68, at 6-9.

⁷⁵ Petitioner seeks to blunt this explanation by urging a lack of legislative awareness of the "product of nature" problem relating to plants. This position cannot be seriously entertained. Fully a third of the Senate Report is devoted to an exhaustive declaration that the work of plant originators constitutes an "invention" rather than a "product of nature." Indeed, the quote from the Senate Report appearing in the text at page 32 of Petitioner's brief, reporting a clear distinction between the discovery of a new variety of plant and discovery of inanimate things such as minerals, was an effort to distinguish new plants from *products of nature*, not from things that were not "alive," as suggested by Petitioner. The quoted passage next notes: "The mineral is cre-

A second rational explanation for enactment of the Plant Patent Act relates to the relaxation of certain formal requirements which had commonly been viewed as imposing substantial impediments to patenting complex organisms such as plants.⁷⁶ This relaxation is evidenced by the amendment to R.S. 4888 by the Plant Patent Act of 1930 to reduce the disclosure requirements for plant inventions.

The question has been raised by Petitioner, however, as to why, if Congress simply sought to relax the disclosure requirements, it was necessary to amend both R.S. 4886 and R.S. 4888. A plausible answer lies in the recognition that amendment of R.S. 4886 to add the

ated wholly by nature unassisted by man." *Senate Report, supra* note 68 at 7. More significantly, even Petitioner concedes that the realization that plants simply found in nature, i.e., products of nature, had to be excluded from any plant patent legislation occurred *during* the legislative process leading to passage of the Plant Patent Act of 1930. Pet. Brief at 34-35.

⁷⁶ See, e.g., the remarks of Commissioner of Patents T. E. Robertson, commenting on S. 3530, the first Senate bill to amend R.S. 4886 to specifically describe plants. Incorporated in a letter of Secretary of Commerce R. P. Lamont read by Chairman A. H. Vestal in hearings before the House Committee on Patents on H.R. 11372, 71st Cong., April 9, 1930, it states that the written description of a plant filed in the Patent Office would be useless and hence could not satisfy the disclosure requirements then embodied in R.S. 4888. See also authorities quoted in note 64, *supra*.

The remarks of Commissioner Robertson are cited as probative of the existing state of the patent law and must be distinguished from the remarks on the same topic by Secretary of Agriculture Hyde quoted above. Commissioner Robertson was the administrative official directly charged with and having experience in administration of the patent laws. As noted by the Ninth Circuit Court of Appeals in a slightly different context, "Courts accord 'great weight' only to the interpretations given a statute by the agency charged with the statute's administration." *Hamilton v. Butz*, 520 F.2d 709, 714 (9th Cir. 1975).

phrase "or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant . . ." provided the logical antecedent for the amendment of R.S. 4888 to exempt all "plant patent[s]" from the prevailing disclosure requirements. In order to avoid inclusion of *all* plants, including certain politically controversial sexually reproduced and tuber-propagated plants, within the R.S. 4888 exemption, it would have been necessary to *exclude* certain plants from the existing scope of patentable inventions. Given that the exempted and non-exempted classes of inventions had to be defined somewhere, it was eminently sensible to define those classes in the section of the statute where other groups of inventions were already defined.

It is apparent from the foregoing that the legislative history of the Plant Patent Act is, in all respects, at most neutral on the perceived status of microorganisms under the existing patent law. The legislative history reflects preoccupation with two problems which had to be overcome to allow plants, in the lay sense of the term, to partake of all of the benefits of the patent system—a declaration that they were not products of nature and exemption from disclosure requirements. Petitioner concedes that the Chakrabarty microorganism is not a product of nature, and does not challenge the validity of the practice under *Argoudelis, supra*, whereby the disclosure of the Chakrabarty microorganism was made to conform to existing disclosure requirements. Accordingly, the plethora of material relating to solution of the problems with plants is of no value in determining how microorganisms should be treated under antecedent statutory language.

IV. CONCLUSION

Rcent months have witnessed a multitude of expressions of concern—in the press, in Congress and by the Executive Branch of the government—about the decline of industrial innovation in the United States. Given the vast potential of living organism technology for solving many of the ills besetting the country and for contributing significantly to a turnaround of the innovation crisis, it would be tragic indeed if this Court were to accept the “sky-is-falling” arguments of *Amicus* PBC or the tortured and slavishly technical arguments of Petitioner against its patentability in the abstract. *Amicus* PMA submits that this result need not—and, more importantly, should not—be reached.

Respectfully submitted,

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IN THE

Supreme Court of the United States

October Term, 1979

No. 79-136

SIDNEY A. DIAMOND, Commissioner of
Patents and Trademarks,
Petitioner,

vs.

ANANDA M. CHAKRABARTY,
Respondent.

**On Writ of Certiorari to the United States
Court of Customs and Patent Appeals**

**BRIEF ON BEHALF OF THE AMERICAN PATENT
LAW ASSOCIATION, INC., *AMICUS CURIAE***

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**BRIEF ON BEHALF OF THE AMERICAN PATENT
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I.

Question Presented

Whether a man-made microorganism, having unique and useful properties which do not exist in nature, fails to constitute a composition of matter or manufacture under 35 USC §101 solely because the entity also demonstrates the characteristics of life.

II.

Identity of *Amicus*

The American Patent Law Association, Inc. (herein the "Association") is a professional association of over 4,000 lawyers throughout the United States interested in the laws relating to patents, trademarks, copyrights, and unfair competition. Its members constitute approximately half the practicing patent lawyers in the country, from private, corporate, and governmental practice. One of the objects stated in the Association's Articles of Incorporation is to aid the courts in the proper interpretation of the laws relating to patents, trademarks, copyrights and unfair competition.

The consent of the parties' counsel to the filing of this brief has been obtained and will be separately filed with the Court.

III.

Interest of *Amicus*

The Association has no concern with, and expresses no views on, the private interests of the respondent in this appeal. The Association has a strong and continuing interest in the administration of the patent laws and seeks to provide aid to this Court in reaching an interpretation of the patent statutes which will further the public interest expressed in article I, section 8, clauses 8 and 18, of the Constitution which, in pertinent part, reads:

The Congress shall have Power . . . (8) To promote the Progress of Science and useful Arts, by securing

for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . . And (18) To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers . . .¹

IV.

Statute Construed

35 USC §101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

V.

The Position of the Association as *Amicus Curiae*

This case presents an important question with respect to the nature of things which may receive patent protection under the Patent Statutes. The question must be resolved in a manner consistent with firmly established and basic principles of law and in the public interest.

Respondent's invention is in the field of science variously referred to as genetic engineering or molecular biology, an evolving technology which has made remarkable advances during the past decade.

1. U.S. CONST. art. I, §8, cls. 8 and 18.

Recently, the synthesis of the mammalian hormone insulin, a complex protein, by a strain of genetically modified bacteria was reported,² thereby promising a plentiful and inexpensive source of this substance, indispensable to diabetics but heretofore available only from animals. The next ten years are expected to bring even more startling advances. It was recently announced that the antiviral substance "interferon", a substance known for over twenty years but heretofore available in such minute quantities as to preclude widespread use, has been produced by genetically modified bacteria.³ Another recent *New York Times* article⁴ quoted one scientist as seeing industrial applications of molecular biology "far beyond medical practice and drug innovation", with research teams "working on projects aimed at such diverse applications as energy, industrial chemical production, agriculture and even forest products". Indeed, respondent's invention is directed at the degradation of oil in oil spills.

This new technology, science or art by which man can create new entities which never existed in nature holds vast promise for all of mankind. *Amicus'* concern is thus not whether the present respondent should have a patent, but whether 35 USC §101 should be construed so that "progress" in a new and vastly useful art will be "promoted", in accordance with the Constitutional authority under which the statute was enacted.

2. Wall Street Journal, Sept. 7, 1978, at 16. No strain of bacteria found in nature is known to produce insulin.

3. N. Y. Times, Jan. 17, 1980, at 1, col. 1.

4. Schmeck, "Molecular Biology Takes Over Where Evolution Left Off", N. Y. Times, Dec. 30, 1979, §DX at 9, col. 1.

VI.

Summary of Argument

The court below, without question the only appellate court in this country involved on a virtually day-to-day basis in the construction and application of the patent statutes, has twice construed 35 USC §101 with respect to respondent's invention. The second holding, the case now before this Court, was made only after thorough reconsideration in view of this Court's opinion in *Parker v. Flook*, 437 U.S. 584 (1978), and an exhaustive evaluation of each argument advanced by petitioner.

Petitioner sees in the depth of that reconsideration by the lower court some sort of defiance and urges, largely on the basis of *in terrorem* pleas in the name of public safety, philosophic controversy and invocation of "monopoly" charges, that the holding of the Court of Customs and Patent Appeals was in error.

The arguments which follow are offered in the belief that petitioner is in error in its position. *Amicus* submits that the evaluation of whether 35 USC §101 is satisfied by a particular entity under consideration does not involve a determination of whether "aliveness" can be found in that particular entity. To hold that it does will read into the statute a limitation that cannot be found in the language of the statute, and no convincing evidence has been advanced to demonstrate that Congress intended such limitation.

Secondly, it is the position of *amicus* that this case does not involve an extension of patent rights; 35 USC §101 was drafted by Congress to apply to new technologies, almost by definition unforeseeable. Further, §101 has been correctly applied by the Patent and Trademark Office to permit patenting of processes utilizing microorganisms. It is inconsistent and illogical to exclude the novel and operative entity itself from the category of things which may be the subject of patents.

Thirdly, *amicus* urges that the lower court's holding is fully consistent with and follows this Court's view that laws of nature, abstract concepts, and scientific truths are not patentable.

Finally, *amicus* urges that the Plant Patent Statute of 1930 is an insufficient basis for defining Congressional intent in 1874, and that the *in terrorem* arguments of petitioner are misleading and beside the point.

The President of the United States, in a recent message to Congress,⁵ acknowledged that innovation in this country is badly in need of stimulation, and outlined a program intended to correct this national concern. Two of the nine critical areas addressed by the President were those of Enhancing the Transfer of Information and Strengthening the Patent System. It is the Association's view that if petitioner succeeds, the President's programs will receive a serious setback, and secrecy will be encouraged. Such a result is not in the public interest.

5. President's Message to Congress of the United States, 15 Weekly Comp. Of Pres. Doc. 2069 (Oct. 31, 1979).

VII. ARGUMENT

A. The determination of whether 35 USC §101 is satisfied does not involve "aliveness".

Petitioner has stated that the "Question Presented" to this Court is "Whether a living organism is patentable subject matter under 35 USC §101".⁶

Framed in this manner, the question tends to evoke an almost reflexive negative response. The reason for this response lies, however, not in an express or even identifiable legislative exception to the objective of article I, section 8 of the Constitution to "promote the useful Arts". Rather, the response is evoked by a common belief that any and all things which exhibit the characteristics of life are, and of necessity exclusively must be, phenomena of nature. Until the last decade, all "living organisms" were, in fact, phenomena of nature.

Since phenomena of nature are not patentable, *Gottschalk v. Benson*, 409 U.S. 63 (1972), one tends almost subconsciously to complete the syllogism by concluding that if products of nature are not patentable and living organisms are products of nature, living organisms are not patentable.

Insofar as the patent law is concerned, however, the patent-defeating characteristic of a phenomenon of nature is not its "aliveness". It is, rather, its prior existence without the intervention of man. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). A chemical compound, for example, which is produced in nature has been held to be unpatentable. *Cochrane v. Badische Anilin Soda Fabrik*, 111 U.S. 293 (1864). That chemical compound,

6. Brief for Petitioner at 3.

however, was never "alive". The bar to its patentability, and for any phenomenon or product of nature, involves nothing more than a lack of novelty. In *Funk*, this Court stated:

For patents cannot issue for the discovery of the phenomena of nature. See *Le Roy v. Tatham*, 14 How. 156, 175. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery it must come from the application of the law of nature to a new and useful end.⁷

Today, however, "things alive" cannot be equated automatically and invariably to "products of nature". Today, the technology or art of genetic engineering is producing "things alive" which are made by man, not by nature. While these creations demonstrate the properties of "aliveness", they are not products of nature. They are products of man, products which serve the new and useful ends to which the court referred in *Funk*.

The new and useful ends served by respondent's invention were achieved by man. Respondent did not discover a phenomenon of nature but *created* a phenomenon which does not exist in nature.

7. *Funk Bros.*, *supra*, 333 U.S. at 130.

Similarly, the recently announced synthesis of an entity capable of producing insulin can under no stretch of the imagination be characterized as a mere discovery of a phenomenon of nature. No strains of bacteria, as "created" by nature and which have always existed, are known to produce insulin. That new and useful capability was achieved by man, by successfully splicing genetic material into the existing genetic material of the bacteria, producing a new phenomenon, a product of man, not a product of nature. Significantly, the extrinsic material inserted into the cell was chemically synthesized in a laboratory by man; it was not "naturally" produced. A microorganism capable of producing insulin is not a "product of nature" since, in nature, microorganisms are not known to produce insulin.

Petitioner would, however, seek to preemptively deny patentability through judicial insertion into the statute of the admittedly emotional but totally irrelevant term "life".

Numerous judicial bodies have grappled in other contexts with the immense problem of simply defining "life". The moral and ethical implications inherent in those situations, where a legal definition of life carries with it a legal definition of death, are not present here. There is only the express objective of promoting useful arts in article I, section 8 of the Constitution, and the absence in the patent statute of any prohibition against "living" inventions.

Petitioner's attempt to interpret §101 by judicial insertion of an exclusion based solely on some life or "vital force" factor, moreover, ignores the fact that Congress already has provided statutory tests, novelty under 35 USC

§102 and unobviousness under 35 USC §103, by which patent protection for true products of nature can be precluded, be they “alive” or “dead”. Living organisms produced by nature cannot be protected by issuance of a patent if these express statutory tests are not satisfied. *Amicus* would thus note that finding subject matter to fall within the categories of 35 USC §101 does not mean that subject matter is *per se* patentable, i.e., that a patent will necessarily issue. The right to a patent under §101 of Title 35 is expressly “subject to the conditions and requirements of [Title 35]”.⁸

The lower court did not and could not pass on whether or not respondent had made a “patentable” invention or disclosed a “patentable” invention in respondent’s application when measured by these express statutory tests. Petitioner raised no issue before the lower court concerning the novelty of the invention under the detailed requirements of 35 USC §102, its nonobviousness under 35 USC §103, or the adequacy of the application’s disclosure under 35 USC §112. The lower court was required to consider the cases on the assumption that respondent had been found to be in compliance with each of these statutory requirements. The court below thus characterized the sole issue, as placed before it by respondent, as to whether an invention otherwise patentable under the statute is excluded from the categories of patentable subject matter set forth in §101 simply because it is alive.

Amicus takes no position on the eventual patentability of respondent’s invention under the existing and express

8. 35 USC §101.

statutory requirements of 35 USC §§101, 102, 103 and 112. By the language utilized in all of those sections, Congress, “. . . making all laws which shall be necessary and proper . . .”,⁹ has clearly delineated *all* the conditions of patentability. A new and highly useful technology should not be denied the right to demonstrate satisfaction of those express conditions through introduction of a term not appearing in the statute.

The position expressed in the Petition to this Court glosses over the statutory language by which Congress expressly set forth the conditions of patentability, and emphasized instead “living”, a condition which is not in the statute:

Living things—whether *naturally occurring, isolated, or genetically engineered*—are no more “discoveries” of the kind the statute was enacted to protect than are the mathematical principles involved in *Flook*. [emphasis added.]¹⁰

By grouping “genetically engineered” with “naturally occurring” petitioner would cast upon genetically engineered subject matter, an article of manufacture, the shadow of unpatentability associated with naturally occurring subject matter, true products of nature. The unpatentability of naturally occurring subject matter, however, as already noted, is a consequence of 35 USC §102, not 35 USC §101. Something “naturally occurring” is not patentable simply and solely because of a lack of novelty.

9. U.S. CONST. art I, §8, cl. 18.

10. Petition for Writ of Certiorari at 439 BNA, Pat. T.M. Copyr. J., D-1, D-4 (August 2, 1979).

Certainly Congress did not intend naturally occurring subject matter, something which always existed, to be patentable. That is one of the express purposes of §102.

If patentability is to be foreclosed, without any inquiry into utility, novelty or unobviousness, solely on the grounds that a manufactured entity is "alive", it necessarily follows as a corollary that only inanimate entities can achieve patentability under the law as it now stands. The characteristics upon which this distinction is made would appear to be irrelevant to the ultimate objective of the Constitution and the patent statutes enacted thereunder. Animate objects are generally distinguished from inanimate objects on the basis of metabolism, growth, reaction to stimuli and reproduction. It is precisely because these characteristics can be retained while at the same time new results are obtained that genetically engineered organisms represent such progress in the art. In the case of respondent's invention, for example, it might be theoretically possible to harvest from separate microorganisms the individual enzymes responsible for the different degradative pathways and to formulate an inanimate composition which would perform, at least temporarily, the same conversions which the claimed entity achieves. Not being alive, such a hypothetical composition could qualify under 35 USC §101 under petitioner's test (whether it would qualify under §§102 and 103 are, as has been noted, separate questions). The same might also be possible by simply "killing" respondent's new microorganism. While these hypothetical "manufactures" would be performing the same metabolic conversion, albeit without the benefit of a "vital life force", they would do so only momentarily and without the advan-

tage of reproduction and regeneration designed into the entity. To require a useful manufacture to be made essentially useless in order to qualify as patentable subject matter would reduce the law to an absurdity.

B. This case does not involve an extension of patent rights.

In *Parker v. Flook*, *supra*, this Court noted that "[W]e must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress",¹¹ quoting a passage from the opinion of Mr. Justice White for the majority in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972) which stated:

We would require a clear and certain signal from Congress before approving the position of a litigant who, as respondent here, argued that the beachhead of privilege is wider, and the area of public use narrower, than the courts had previously thought. No such signal legitimizes respondent's position in this litigation.

In the portion of the paragraph in *Deepsouth* which just precedes the passage quoted above, the Court stated:

It follows that we should not expand patent rights by *overruling or modifying our prior cases* construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language. (emphasis added.)¹²

As recognized correctly by the court below, the present case does not present a litigant urging a construction of 35

11. 437 U.S. at 596.

12. 406 U.S. at 531.

USC §101 which is at odds with established precedent. Rather, this is a case of first impression. Since the Court is not being asked to make a change in existing law or to overrule or modify any case or to expand any rights given by Congress, there is no need for a signal from that body.

What is involved here is not an expansion of patent rights. Respondent's patent rights would be identical to those of any other patentee. What is involved is an expansion of science and technology, the very progress envisioned by the Constitution. Petitioner's attempt to preclude patentability to such scientific and technological progress seems singularly incongruous with the objectives set forth in the Constitution.

It is not necessary that Congress must foresee each new field of technology or useful art to bring it within §101. As the Court stated in *Barr v. United States*, 324 U.S. 83, 90 (1945),

... if Congress has made a choice of language which fairly brings a given situation within a statute, it is unimportant that the particular application may not have been contemplated by the legislators. *Puerto Rico v. Shell Co.*, 302 U.S. 253, 257, *Browder v. United States*, 312 U.S. 335, 339, and cases cited.

Clearly, the language which Congress chose to use in §101 brings respondent's invention within the statute. As the court below noted:

To insist on specific Congressional foresight in construing §101 would be the very antithesis of the Constitutional and Congressional purpose of stimulating the

creation of new technologies—by their very nature unforeseeable—and their progressive development. This has been clear since *Kendall v. Winsor*, 62 U.S. 322, 328 (1859) wherein the Supreme Court said:

The true policy and ends of the patent laws enacted under this Government are disclosed in . . . article [I] of the Constitution, the source of all these laws, viz: "to promote the progress of science and the useful arts," *contemplating and necessarily implying their extension and increasing adaption* to the uses of society. [emphasis ours.]¹³

Except for the substitution of the word "process" for the word "art", the language appearing in 35 USC §101 has been the same ever since the Patent Act of 1793. The terms "manufacture" and "composition of matter" are first found in the Patent Act of 1793. In all the time since then, those words have been liberally construed to include the most diverse range of unforeseen technological developments imaginable—telephones, radios, television, automobiles, radar, lasers, antibiotics, microcalculators, atomic energy, polio vaccines, and pacemakers. The list is endless and beyond recitation. Neither the Founding Fathers nor the Congresses which drafted the patent statutes could have foreseen the innumerable subsequent innovations.

What was foreseen was not the specific scientific and technical areas in which progress would be made but the fact that progress itself would be made and should be encouraged.

13. *Application of Bergy, Coats, and Malik; Application of Chakrabarty*, 596 F.2d 952, 973 (C.C.P.A. 1979).

C. The lower court's holding is fully consistent with and follows this Court's view that laws of nature, abstract concepts, and scientific truths are not patentable.

It is beyond dispute that intangible laws of nature, scientific principles and mathematical equations are outside the ambit of patentability. *Parker v. Flook, supra*. The underlying notion was stated by the Court in *Flook* to be that "[A] scientific principle . . . reveals a relationship that has always existed."¹⁴ Quoting from Rosenberg,¹⁵ the Court noted:

The reason is founded upon the proposition that in granting patent rights, the public must not be deprived of any rights that it therefore freely enjoyed.¹⁶

The patentability of the respondent's invention in no way conflicts with this principle since it never existed until the respondent made it. The public, as a result of the respondent's industry, now can enjoy the fruits of that labor but the public had *nothing* to enjoy, freely or otherwise, prior thereto.

The holding of *Parker v. Flook, supra*, that laws of nature, abstract concepts and scientific truths are not patentable is essentially a reaffirmation of principles approved by this Court in earlier cases. In *Mackay Radio and Telegraph Co. v. Radio Corporation of America*, 306 U.S. 86 (1939), involving the patentability of a directional antenna

14. 437 U.S. at 593, n.15.

15. P. Rosenberg, Patent Law Fundamentals §4, at 13 (1975).

16. 437 U.S. at 593, n.15.

system in which the wire arrangement was determined by the logical application of a mathematical formula, it was stated:

While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.¹⁷

In *Funk Bros. Seed Co. v. Kalo Inoculant Co., supra*, this Court held claims to a physical combination of mutually noninhibitive strains of bacteria, each of the bacterial strains having been previously known and separately used, for the same purpose, unpatentable, stating:

The combination of species produces no new bacteria, no change in the six species of bacteria and no enlargement of the range of their utility. Each species had the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.¹⁸

Consistent with this test is the holding of this Court in *American Fruit Growers, Inc. v. Brogdex*, 283 U.S. 1 (1931), namely, that a naturally occurring object becomes a manufacture only when it is given "a new or distinctive form, quality, or property."¹⁹

17. 306 U.S. at 94.

18. 333 U.S. at 131.

19. 283 U.S. at 11.

This test, stated by this Court to point to the proper analysis in *Flook*, has been followed by other lower courts and was followed by the CCPA in this case.

In *Merck & Co., Inc. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156 (4th Cir. 1958), the Fourth Circuit Court of Appeals made specific reference to the test set forth in *Funk Bros.*:

In dealing with such considerations, unpatentable products have been frequently characterized as "products of nature." See *Funk Brothers Seed Company v. Kalo Inoculant Company*, . . . (a composite culture of non-inhibitive strains of different but known, species of bacteria); [additional citations omitted]. But where the requirements of the Act are met, patents upon products of nature are granted and their validity sustained.²⁰

Significantly, in upholding a patent to a vitamin B-12 active composition over a product-of-nature defense, the Fourth Circuit Court of Appeals held that:

The compositions of the patent here have all of the novelty and utility required by the Act for patentability. They never existed before; there was nothing comparable to them . . . The new products are not the same as the old, but new and useful compositions entitled to the protection of the patent.²¹

The court below fully appreciated and applied this test in reaching its carefully reasoned opinion, as is clear from Judge Baldwin's statement in his concurring opinion:

20. 253 U.S. at 162.

21. 253 F.2d at 164.

Although many of these decisions are far removed in time, and involve crude technologies when compared to those of Bergy and Chakrabarty, the opinions supporting these decisions voice a concern of the Supreme Court that a patentee not obtain an effective monopoly over that which is called, for the lack of a more precise term, "a principle or phenomenon of nature". The common thread throughout these cases is that claims which directly or indirectly preempt natural laws or phenomena are proscribed, whereas claims which merely utilize natural phenomena via explicitly recited manufactures, compositions of matter or processes to accomplish new and useful end results define statutory inventions.²²

If, as this Court has stated, the *Mackay* and *Funk* approaches pointed to the proper analysis to be used in *Flook*, they present *a fortiori*, the proper analysis for respondent's invention. Respondent's new, man-made strain of a micro-organism having the new and useful end of simultaneously degrading several different components of crude oil is a novel and useful structure according to *Mackay*, which enlarges the range of utility according to *Funk*.

D. The Plant Patent Statute of 1930 is an insufficient basis for determining Congressional intent in 1874.

Petitioner contends that the Plant Patent Act of 1930²³ is a basis for the exclusion of the respondent's invention from §101. However, petitioner is mistaken in its

22. *Application of Bergy et al*, *supra*, 596 F.2d at 988.

23. 35 USC §161 *et seq.*

reliance on this basis for it has looked to the legislative history of the Plant Patent Act for evidence of the intent of a previous Congress, saying in effect that if Congress in 1930 passed an act extending patent protection to the plant breeders, then Congress in 1874 must not have intended that "manufactures" and "compositions of matter" in R.S. §4886 include any living organism. This ascribes to a preceding Congress an intent which the members of that Congress did not themselves state. As this Court has noted, "[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *United States v. Price*, 361 U.S. 304, 313 (1960).

The plant protection legislation was enacted not because the subject matter was "living" but rather because the statutory description requirements of the then-existing patent act were such that they could not be met by, and thus inhibited the promotion of, the useful art of plant breeding. A contemporaneous memorandum from the Commissioner of Patents to the Secretary of Commerce shows that it was this difficulty in providing a sufficient description of the to-be-patented plants, and not the fact that the plants were alive, which precluded their patenting under the then-current statute:

Further, and more important, there at once arises the difficulty of defining in a written document which must be printed, both as constituting part of the patent and as constituting a publication available for search and distribution, the differences which identify a new variety from previously known varieties.²⁴

24. A Bill to Provide for Plant Patents: Hearings on H.R. 11372 before the Comm. on Patents 71st Cong., 2d Sess. 7 (1929-30) (statement of Hon. Fred S. Purnell).

The reaction of Congress was the relaxation of the description requirement as a means of constitutionally "promoting" the "useful art" of plant breeding. The bill, as passed, included the provision that "[n]o plant patent shall be declared invalid on the ground of non-compliance with this Section [§§4888-35 USC §33 (1930)] if the description is made as complete as is reasonably possible." Thus, the only operative phrase in the Plant Patent Act relevant here, 35 USC §162, as enacted, relates to description, not to "life".

E. *In terrore* arguments of petitioner are misleading and beside the point.

Petitioner has found it necessary in its brief to argue the "highly controversial"²⁵ nature of research in this area, involving as it does "recombinant DNA"²⁶ and "genetic engineering".²⁷ The controversy is urged, in part, by an exposition on the hazards involved in research in this area. Without question, the research is not free from hazard. Neither is research in a chemical laboratory, laser research, research into the structure of the atom or fission, or myriad other lines of research. But the degree of hazard connected with research in a particular area of technology, old or new, is not the standard. No authority is cited to the contrary. The Patent and Trademark Office well knows that its function is to *examine* inventions presented to it for compliance with the patent statutes, not to *regulate* hazardous research.

As evidence of the hazards involved, petitioner relies heavily on NIH Recombinant DNA "Guidelines", of 1976.²⁸

25. Brief for Petitioner at 18.

26. *Id.* at 17.

27. *Id.* at 18.

28. *Id.* at 19.

These guidelines were considerably relaxed in 1979 by the National Institutes of Health which reportedly currently fund over 700 scientific projects in this area, involving over 90 million dollars.

Another point made by petitioner on the subject of "controversy" raises the specter of slavery, and questions whether such life can be "owned"²⁹ by patent holders. Fortunately, the specter is quickly laid to rest by reference to the Thirteenth Amendment.³⁰ Granted, patent rights are personal property rights. However, there is no justification under our laws known to *amicus* for a distinction between property rights in living things as opposed to non-living things. Valid property rights in living entities have been recognized as long as humans have existed, from the domesticated goat and plots of Indian corn to today's vast herds of sheep, cattle and pigs and vast fields of wheat. Consider, too, the prize bull whose owner, by virtue of a "monopoly" and current technology, earns a good profit while at the same time providing a dairy farmer with an opportunity to improve his herd. Also consider the syndication of race horses. These are all examples of valid property rights held by citizens of this country in living entities. One must ask why the Patent and Trademark Office, through the office of Solicitor General, seeks to have patent rights in living things set apart as some special breed of property right. Petitioner's brief provides no support for this position.

29. *Id.* at 20.

30. U.S. CONST. amend. XIII, §1.

Still another argument is made based on the "confining monopoly"³¹ theory. If understood correctly, petitioner's argument here seems to say that strict construction of 35 USC §101 is required on the characterization of a patent as a monopoly. One consequence of this argument would be that patents would be granted only for advances in areas of existing technology, a result clearly at variance with the expressed aims of the Constitution—"To promote the Progress of . . . useful Arts."³²

More disturbing is the need for petitioner to defend its position in this case by invoking "this Nation's historical antipathy to monopoly,"³³ which suggests an antagonism to our patent system as a whole, rather than recognizing this nation's historical, and Constitutionally recognized, commitment to the promotion of progress through the grant of patents.

Two additional arguments made by petitioner on the commonly perceived scope of the present patent statutes require comment. The first is to the effect that various bar associations and their committees have proposed legislation over recent years "so that various living things, including microorganisms, might at last be patented."³⁴ *Amicus* merely observes that to the extent that this showing can be relied on, it must be considered as a reaction by the organized bar to the rejections of patent claims under the then current practices of the Patent and Trademark Office.

31. Brief for Petitioner at 12.

32. U.S. CONST. art. I, §8, cl. 8.

33. Brief for Petitioner at 12.

34. *Id.* at 14.

When faced with such action by a government bureau, the public has two choices, one is to seek redress from the courts and the other is to seek corrective legislation. The choices are not mutually exclusive. As this Court is well aware, even if it devoted its full time to hearing cases where the government takes a different view of the law than a private citizen, it could hear and decide only a small fraction of the disputes. What the petitioner attempts to rely on can be promptly dismissed as the pragmatic efforts of the organized bar, through Congress, to correct an extreme misinterpretation of §101 by the Patent and Trademark Office, and nothing more.

It should also be noted that much of the substance of the various bar association activities footnoted by petitioner relates to the desirability of relaxing for agricultural arts the standards set by §112. 35 USC §112 sets forth rather strict standards which must be met by an inventor when describing his invention.

Petitioner urges that Congress did not intend to include living things themselves within the scope of the general patent laws. But note claim 30 of petitioner's application, already allowed by the Patent and Trademark Office, which is clearly directed to the "living thing itself," albeit in combination with a carrier such as straw able to float on water and absorb oil. The bacteria is no less living because it is associated with the carrier, and in fact must be living in order to function in the manner intended by the invention. Further, as pointed out by the court below, the Patent and Trademark Office has construed the term "manufacture" in the statute to include yeast at least as early as 1873 in a

patent granted to Louis Pasteur. Other typical patents listed by the court, significantly granted in the period subsequent to 1930 include bacteria, mushroom mycellia, plant seeds, eggs, and eggs plus bacteriophages.

In its brief, petitioner attempts to blunt this argument by characterizing the long line of patents to living things as "aberrant." First, neither the parties nor *amici* attempted to collect all patents of this nature, and the court below listed only a few typical examples. More to the point, there is no evidence whatever to establish that such patent grants were aberrant or that petitioner was in any way aberrant in granting the patents. This record more reasonably can be interpreted to the effect that patents to a variety of living things were issued as a matter of course until, for reasons not appearing in the record (but wondered about in the opinion of the court below), the policy of the Patent and Trademark Office abruptly changed. As noted by Chief Judge Markey in his concurring opinion in the first *Chakrabarty* decision:

[I]f our patent laws are to achieve their objective, extra-legal efforts to restrict wholly new technologies to the technological parameters of the past must be eschewed. Administrative difficulties, in finding and training Patent and Trademark Office examiners in new technologies, should not frustrate the constitutional and statutory intent of encouraging invention disclosures, whether those disclosures be in familiar arts or in areas on the forefront of science and technology.³⁵

Amicus submits that 35 USC §101 in its present form is adequate fully to include new areas of technology as they

35. *Application of Chakrabarty*, 571 F.2d 40, 44 (C.C.P.A. 1978).

develop. It has served well in this capacity in the past, and this Court is urged to continue its effectiveness by affirming the holding of the court below.

Conclusion

For the reasons stated hereinabove, the judgment of the Court of Customs and Patent Appeals below serves the public interest and adheres to the established principles of statutory construction, and therefore, should be affirmed.

Respectfully submitted,

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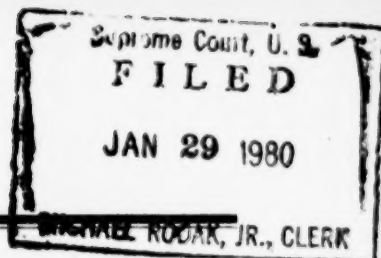
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1979

No. 79-136

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, *Petitioner,*

v.

ANANDA M. CHAKRABARTY, *Respondent.*

**BRIEF OF DR. GEORGE PIECZENIK
AS AMICUS CURIAE**

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**BRIEF OF DR. GEORGE PIECZENIK
 AS AMICUS CURIAE**

I. INTEREST OF THE AMICUS

Dr. George Pieczenik, appearing herein as *amicus curiae*, is a molecular biologist and computer scientist on the faculty of Rutgers University. Dr. Pieczenik received his undergraduate training at Harvard University, obtained a masters degree in radiation physics from the University of Miami, and a doctor of philosophy degree from New York University. His doctoral dissertation was entitled "Genetic Code Constraints on Amino Acid and Nucleotide Sequences," in which he investigated the genetic code of living organisms from the standpoint of a language having internal

constraints and internally consistent syntax. These studies, in combination with subsequent work carried out at Rockefeller University and the M.R.C. Laboratory of Molecular Biology, Cambridge, England, have consequences in molecular biology which received national press coverage (*Time*, April 4, 1977, p. 47). Dr. Pieczenik has been one of the pioneer scientists in the development of techniques for determining nucleotide sequences of DNA and RNA, and has developed techniques for the construction of transfer vectors in recombinant DNA technology which are the subject of a pending patent application. A list of his scientific publications is attached hereto as an Appendix. Dr. Pieczenik has no financial interest in or connection with Respondent.

Dr. Pieczenik has been active in public affairs relating to science and technology in his area of expertise. In this regard, he has testified before the Committee on Science and Technology of the House of Representatives on matters relating to the safety of recombinant DNA research.

Dr. Pieczenik is concerned that the decision in the instant case be made along lines that are rational and meaningful in terms which he and other researchers similarly situated can comprehend as guidelines for what may or may not be patented in this area of technology. He is further concerned that the Court should have the benefit of direct input from research workers in this art with respect to the nature of the inventions likely to be affected by its holding and the consequences thereof as applied to the existing patent statute.

II. STATEMENT AND ARGUMENT

The Petitioner requests reversal of the decision below *on the ground that the subject matter is a living organism*. Whatever this Court's holding, its decision will necessarily distinguish between patentable and unpatentable subject matter in the area of biotechnology. It is essential that this line be drawn on the basis of the known scientific realities as applied to the existing law. This Court is not constrained to accept the conceptual framework suggested by the Petitioner.

The distinction between living and non-living matter has no real meaning in relation to this technology. That which is living is typically described in terms of a set of attributes¹ which, when all present, are considered indicia of life. There is no single fundamental property, law of nature, or operating principle, which distinguishes that matter which we call living from that which we do not.² To attempt to separate

¹ See, for example, Luria, S. E. and Darnell, James D., Jr., *General Virology*, 2nd Edition, John Wiley & Sons, Inc., New York, 1967, pp. 5-8. Commonly mentioned attributes include cellular organization, ability to derive energy from sources in the environment, motility, responsiveness to change in environmental conditions, capacity to replicate, and so forth.

² The notion of vitalism holds that, in the last analysis, the phenomena of life can be explained only by the existence of a mysterious "vital force" which operates only within the realm of living matter. Gunther Stent, in his text *Molecular Genetics*, (W. H. Freeman & Co., San Francisco, 1971, p. 28), notes that a sophisticated version of vitalism may have inspired the interest which many physicists took in biological phenomena following World War II:

Inspired by the romantic notion of finding "other laws of physics" through the study of genetics, a number of physical scientists left the occupation for which they had been trained

patentable and unpatentable subject matter on the basis of such a concept is to invite confusion in the art, to ignore existing law and to ignore scientific reality.³

Amicus therefore invites the Court to consider how the line can best be drawn, irrespective of its ultimate holding, for it is this aspect of the case which will determine whether the decision offers meaningful precedential value for researchers, the Patent and Trademark Office and for the Court of Customs and Patent Appeals, or whether it invites confusion, uncertainty and continued litigation. A definitive decision, *based on practical reality*, is urgently needed for future technological advances in this art.

and addressed themselves to the problem of the nature of the gene. The entry of these new men into genetics and cognate fields in the 1940s produced a revolution in biology that, when the dust had cleared, left molecular biology as its legacy. As part of this revolution, molecular genetics was to develop out of classical genetics, and by the time of the Mendel Centennial in 1965 the nature of the gene was understood. Alas, the physicists were to be cheated out of their reward: no "other laws of physics" had turned up along the way. Instead, as the facts to be set forth in this book will show, the making and breaking of hydrogen bonds seem to be all there is to understanding the workings of the hereditary substance.

³ The situation presented in the instant case is to be distinguished from those relating to defining the point at which a human being is legally dead. In such cases, the courts are primarily concerned with matters of social justice involving the point at which the constellation of laws relating to the rights and privileges of a living, sentient individual are to be terminated in favor of the operation of those laws relating to a deceased. In contrast, the instant case relates to the development of biotechnology where the law is concerned only with adjudicating intellectual property rights arising out of new discoveries. Legal decisions in this subject area ought not to be based upon a distinction that has no practical significance in the affected subject area.

Between that which is unquestionably living matter and that which is not, there are a great many useful substances of varying chemical complexity.⁴ In common they are characterized as possessing some of the attributes of living organisms, but they clearly do not possess them all. The viruses for example are typically composed of nucleic acid (DNA or RNA) and proteins⁵ in defined amounts and structural relationships.⁶ In pure form⁷ viruses exhibit no attributes of living organisms, are unable to grow, multiply or derive

⁴ A partial list would include such obligate parasites as the *Chlamydia* and *Bdellovibrio bacteriovirus* which depend upon some organizational aspect of a living cell for growth and reproduction, the viruses, plasmids (which are composed of DNA) and cloned genes.

⁵ See Luria, S.E. and Darnell, J. D., *supra*, p. 2. The terms DNA, RNA and protein are generic names for polymeric chemical substances. DNA is built up from four monomeric building blocks, termed deoxynucleotides, linked in specific sequential array. It is the sequence of the monomers which chemically distinguishes one DNA from another. RNA is structured similar to DNA except that the monomers are ribonucleotides. The monomeric building blocks of proteins are amino acids, primarily selected from a set of twenty amino acids. Individual proteins are chemically distinguished by the exact sequence of amino acids.

⁶ Typically, the nucleic acid is contained in a core which is surrounded by a coat of protein components. The viruses vary widely in complexity, the simplest having protein coats composed of repeating subunits of a particular protein forming a precise geometric arrangement. The more complicated viruses may include additionally an envelope containing lipid material derived from the membrane of an infected cell. Some of the simpler viruses, for example, bacteriophage ϕ X-174, have been completely characterized chemically, both as to the amino acid sequence of the proteins of the virus and the nucleotide sequence of their nucleic acid component.

⁷ Many viruses have geometrically regular shapes and may be purified in crystalline form.

energy from the environment. When combined with susceptible organisms, a virus can cause the replication and assembly of multiple virus progeny, alter the functional characteristics and even the appearance of the organism and, in some cases can induce permanent genetic alteration of the organism.

Certain kinds of DNA molecules also have a dualistic property of being definable like ordinary inanimate chemical compounds, yet being capable of transforming susceptible host cells, altering their functional properties and inducing permanent genetic changes passed on to progeny cells.⁸ DNA is, in fact, the chemical substance which embodies the genetic information

⁸ Avery, O. T., McCleod, C. M., and McCarty, M., *J. Expt. Med.* 79, 137 (1944), first demonstrated that DNA added to a culture of microorganisms was capable of causing a specific, definable genetic alteration. Despite the fact that DNA molecules are very high molecular weight polymers, most living cells are capable of taking up DNA from the culture medium from which they are grown. Of particular interest in this regard are those DNA molecules termed plasmids. Plasmids are DNA molecules having the ends joined to form a closed loop and contain the necessary genetic determinants for their autonomous replication, once inserted into a living cell. They may, and typically do, contain additional genetic determinants, for example, for resistance to an antibiotic. A bacterial cell may harbor one or more plasmids which replicate autonomously within the cell and are distributed to daughter cells when the cell divides. Novel plasmids containing genes from heterologous sources can be constructed by recombinant DNA techniques or by more conventional microbial genetics techniques. Chakrabarty's organism was derived by a multistep process by which several distinct plasmids bearing various selected genetic determinants were introduced, conferring upon the organism bearing them the ability to metabolize various sorts of hydrocarbons. Selection was "phenotypic," that is, based upon functional properties of the plasmid-bearing organism in defined environments.

of all living organisms.⁹ Its chemical nature is well known and can be found in present day high school biology texts.¹⁰

The essential feature of the chemical structure of concern here is the exact sequence of deoxynucleotide monomers which constitutes a given DNA molecule.¹¹ Deoxynucleotide sequences of specific DNA molecules are now ascertainable as a routine matter with a high degree of accuracy.¹² Furthermore, functional DNA

⁹ The deoxynucleotide sequence of DNA constitutes a code which specifies the amino acid sequences of all proteins made by the organism. RNA, on the other hand, serves a variety of functions intermediate in the process of translating the genetic code into protein. In some instances, RNA also serves as repository of genetic information. In particular, the genetic material of some viruses is RNA rather than DNA.

¹⁰ See, e.g., Otto, J., and Towle, A., *Modern Biology*, Holt, Rinehart and Winston, N.Y. (1977) and Biological Sciences Curriculum Study, *Biological Sciences, an Inquiry into Life*, 4th ed. (1980).

¹¹ A given DNA molecule has a completely definable deoxynucleotide sequence from beginning to end, despite having a molecular weight which may be upwards of hundreds of millions. The number of possible sequences of X monomers is precisely 4^X . In contrast, many patented chemical polymers are only describable in terms of an approximate molecular weight range and have a random arrangement of subunits describable only in terms of their relative proportions. Recently, the complete deoxynucleotide sequence of hepatitis virus DNA was determined. The molecule has 3182 deoxynucleotide subunits and exists in the form of an endless loop. Galibert, F., *et al.*, *Nature* 281, 646 (1979).

A set of endless loop DNA molecules having the same deoxynucleotide sequence could be cut once, at a single site randomly distributed, to yield a population of linear molecules having the same sequence circularly permuted. Such a population is nevertheless uniquely describable in terms of a single sequence, simply by writing the sequence in a circle.

¹² Sanger, F., *et al.*, *Proc. Nat. Acad. Sci. USA* 74, 5463 (1977); Maxam, A. M. and Gilbert, W., *Proc. Nat. Acad. Sci. USA* 74, 560

can be chemically synthesized.¹³ Therefore, DNA molecules, as definable and enumerable pure chemical compounds, fall squarely within the ambit of patentable subject matter under 35 U.S.C. § 101.¹⁴

Further, it is precisely the deoxynucleotide sequence of DNA which accounts for its dualistic nature. The sequence constitutes information to which a living cell is responsive, analogously as an engine to its camshaft or an architect to his blueprints. A DNA molecule introduced into a cell can, in effect, direct the cell to make a protein, according to information encoded in the specific deoxynucleotide sequence of the introduced DNA, and thereby to perform a new function. Furthermore, the introduced DNA molecule can be duplicated manyfold and passed on to progeny cells. The introduced DNA molecule can be reextracted from the cells, many times amplified in amount. For example, bacteria normally sensitive to penicillin can be rendered resistant by introducing into the bacterial cell a DNA molecule which instructs the recipient cell to produce an enzyme that catalytically degrades penicillin. The recipient cell can duplicate the introduced DNA and pass it to progeny cells, so that a new cell strain is

(1977). As a practical matter, the determination of deoxynucleotide sequence of DNA is easier than the determination of amino acid sequence of proteins. It is therefore entirely feasible to deduce the nature of the proteins of an organism from analysis of its DNA. See Galibert, *et al.*, *supra*.

¹³ Itakura, K., *et al.*, *J. Biol. Chem.* 250, 4592 (1975); Itakura, K., *et al.*, *J. Am. Chem. Soc.* 97, 7327 (1975).

¹⁴ It is to be understood that before a patent issued the requisite showing of novelty, utility and unobviousness required elsewhere in the patent statute would be made. The determination on these matters will be dependent upon the facts in each case.

produced, having enhanced survival in an environment containing penicillin.¹⁵

The viruses and DNA molecules themselves share the dualistic property of being chemically definable¹⁶ compositions and propagatable by living cells. Such materials are termed "resurrectable" to signify their ability to alternate between the animate and inanimate realms.¹⁷ Whether existing inanimate in a test tube or functioning within a living cell, the compositions remain chemically definable entities, squarely compositions of matter under § 101.

The resurrectable compositions partake of a second sort of duality, that of being simultaneously chemical compounds and information. The informational aspect is embodied in the deoxynucleotide sequence of DNA,

¹⁵ See Hotchkiss, R. D., Jr., *Unités Biologiques Douées de Continuité Génétique. Colloq. int. Cent. Nat. Rech. Sci.*, 8 57 (1949).

¹⁶ The viruses vary greatly in complexity. As noted *supra*, note 6, some of the simplest viruses have been completely described chemically, in terms of the nucleotide sequence of the nucleic acid component, the amino acid sequences of the protein components, and the structural and geometric relationships between the protein components and the nucleic acid. In the case of more complex viruses, the number of separate protein components comprising the protein coat and some structural features of their assembly have been determined, although the primary sequences of the nucleic acid and protein components have not been determined. The critical question is whether the chemical structure and functional properties of a virus can be described in sufficient detail to enable others of ordinary skill in the art to make and use the invention, as required by 35 U.S.C. § 112.

¹⁷ A class of recombinant DNA cloning vectors derived from bacteriophage lambda has been designated "Charon" phages, after the mythological boatman of the river Styx. Blattner, F. R., *et al.*, *Science* 196, 161 (1977).

which functions as information only within a living cell.¹⁸ This Court has adverted to the informational nature of resurrectable compositions, at least by implication, in its remand of *Parker v. Bergy*¹⁹ for reconsideration in the light of *Parker v. Flook*.²⁰ In view of the essentially chemical nature of cells and resurrectable compositions, and of their tangible, describable properties, the traditional legal principles relating to compositions of matter are necessarily applicable. The relevance of *Flook* to the instant case is therefore viewed as tangential. This Court has viewed askance the patentability of information *per se*²¹ or processes whose essential feature is the manipulation of information.²² However, this is not the case where the patent concerns the physical embodiment²³ of

¹⁸ With the exception that it is technically feasible to demonstrate an aspect of the information content of DNA in a cell-free system comprising extracts of living cells and certain chemical cofactors (Zubay, G., *Ann. Rev. Genetics* 7, 267 (1973)).

¹⁹ 438 U.S. 902 (1979).

²⁰ 437 U.S. 584 (1978).

²¹ *Leroy v. Latham*, 55 U.S. 156 (1852); *O'Reilly v. Morse*, 56 U.S. 62 (1854); *Gottschalk v. Benson*, 409 U.S. 63 (1972).

²² *Parker v. Flook*, *supra*, note 20.

²³ The concept of information, as a property of matter organized in non-random fashion, as quantifiable into "bits," and as transmitted and received according to certain principles, was developed in large part in the pioneering work of C. E. Shannon, *Bell System Tech. J.* 27, 379, 623 (1948), reprinted in Shannon, C. E. and Weaver, W., *The Mathematical Theory of Communication*, University of Illinois Press, Urbana, Ill. (1949). See also Elias, P., "Coding and Information Theory," *Reviews of Modern Physics* (1959), reprinted in *Biophysical Science—A Study Program* (J. L. Oncley, et al, Eds.) John Wiley and Sons, New York (1959) pp. 221-226.

information,²⁴ or processes manipulating an embodiment of information.²⁵ *Flook* did not hold that an otherwise patentable invention would be rendered unpatentable merely because the process or product had an informational aspect. The instant case provides perhaps the most clearly defined opportunity for this Court to distinguish between information *per se* and its embodiment.

The embodiment is a describable chemical compound. It can be manipulated, altered and recombined in novel and unobvious structures. As such, it falls within the category of patentable subject matter under 35 U.S.C. § 101. The fact that it simultaneously bears information is not relevant to its patentability as a product just as that same fact would not negate the patentability of a photographic emulsion or a camshaft. Furthermore, the nature of the information embodied in the deoxynucleotide sequence of DNA is not fully understood. It is a hope of science that a

²⁴ Information may be embodied in a photographic plate, a blueprint, a camshaft, modulated electromagnetic radiation and certain chemical compounds, to give a few simple examples. A second entity (the receiver) is necessary in order to make "sense" of any information. Patented articles involving such physical embodiments are the classic stuff of patents generally.

²⁵ *Cochrane v. Deener*, 94 U.S. 780 (1877); *Dolbear v. American Bell Telephone Co.*, 126 U.S. 1 (1888); *MacKay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86 (1939). The cases cited herein and *supra*, notes 20 and 21, were not decided in specific terms of information or its embodiment, but instead speak of mental steps, mere principles, fundamental laws of nature, algorithms and the like. Viewing these cases in terms of a distinction between information and its embodiment provides a unifying thread running throughout them all, consistent with the general rationale of *Flook*.

fuller understanding of how living cells handle genetic information will be attained.²⁶

The foregoing analysis demonstrates the rationale for patentability of resurrectable compositions that can exist as inanimate chemical compounds, and suggests a boundary condition for such patentability. Substances which are unequivocally living, such as the Chakrabarty organism, are much more complex chemically. They depend for the attributes of life on the proper organized state of their chemical components.²⁷ Furthermore, the living cell exists in a dynamic state in which its detailed chemical composition varies with time and environmental conditions, and probably to some extent, from cell to cell. The living cell lacks the static, uniform aspect which characterizes resurrectable compositions.

Nevertheless, living cells are identifiable and describable entities which can be readily distinguished from one another by a combination of chemical, functional and morphological criteria whose development has reached a highly sophisticated plane in the field of microbiology. As a practical matter, given sufficient

²⁶ Following the rationale of *Flook*, it would not be possible to obtain a patent on the manner with which living cells handle specific genetic information.

²⁷ A living cell is "killed" by disrupting its structure, even though many of the component processes, such as metabolism, can still take place.

The fermentation process (oxidation of sugar to produce ethanol) was considered by 19th century vitalists to be dependent on living cells. It was a disappointment to Pasteur that he was unable to demonstrate cell-free fermentation. However, Eduard Buchner succeeded in 1897 where Pasteur had failed. The secret of Buchner's success lay simply in using a yeast strain in which the cells were more easily broken open.

disclosure of such properties, it would be well within the scope of ordinary skill to distinguish the Chakrabarty organism from similar organisms.

The salient feature of living compositions is their ability to reproduce themselves. Bacteria reproduce with high fidelity and may be stored for long periods of time. These properties are recognized in the current practice of placing the organism on deposit in a public type culture collection.²⁸ The deposit provides an adequate description of the organism even for processes in which the microorganism is arguably the sole element of novelty.

The reproduction of living cells is inherently accompanied by variation in the form of spontaneous mutation and partial genetic exchanges. For bacteria the overall probability of such events is about one in a million per generation.²⁹ As a culture is reproduced over several generations, it is necessary to reisolate the correct organism from a background count of variants which accumulates with each successive generation. In order to accurately identify the desired organism, one must know the criteria by which it was originally selected and these criteria must reasonably insure successful identification. Such criteria will include, for example, the selection process used to isolate the organism initially, its distinguishing functional properties and as many chemical, morphological and functional criteria as are needed to establish identity

²⁸ *In re Argoudelis*, 434 F.2d 1390, (C.C.P.A. 1970).

²⁹ By contrast higher organisms, reproducing by sexual mating, have a probability of variation of nearly 1 (diminished only by the occasional occurrence of identical twins). Certain mammalian cell lines have intermediate levels of variability, on the order of one in a thousand per generation.

according to relevant standards in the art. Therefore, it can be seen that a critical limitation on patenting compositions characterized as "living," is already present in 35 U.S.C. § 112, first paragraph, which requires a description of the invention "... in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same." In terms relevant to this art, compliance with § 112 should include disclosure regarding the organism's function (how to use) as well as its genetic background and selection procedure (how to make), in addition to a deposit of the organism itself.

It follows that holding the instant microorganism to be patentable subject matter will not open the floodgates for the patenting of all sorts of living organisms. The existing statutory framework coupled with the inherent properties of living organisms provides sufficiently cognizable limits, and administrative flexibility, to ensure that the law of patents remains confined to the useful arts, where it has served its function well for nearly 200 years.

III. SUMMARY

In summary, the Government's assertion³⁰ that "the decision to extend the patent laws from the non-living to the living is a policy judgment for Congress to make" is simplistic and misleading. The decision to hold Chakrabarty's organism patentable subject matter or not is a legal question which can and should be decided within the framework of existing statutory and case law. A rational basis can be found to provide

³⁰ Petitioner's Brief, footnote 44.

metes and bounds for a holding on either side of the question.

The field of biotechnology is an emerging useful art with great promise for future benefit to mankind. The constitutional purpose to promote the progress of the useful arts should be applied to promote the progress of biotechnology by providing patent protection. The boundary conditions for patenting living organisms are adequately provided in the existing patent statute, specifically 35 U.S.C. § 112, as discussed herein. Therefore, *Amicus* recommends that the decision of the Court of Customs and Patent Appeals be affirmed but that in any case, the Court's holding provide rational metes and bounds to guide the patenting of subsequent developments in this emerging technology.

Respectfully submitted,

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APPENDIX

APPENDIX A

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